KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452235				
Code:	1013890				
Production Date:	12-2022	**Validity Start Date:**	12-2022	**Expiry Date:**	11-2025
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Test	Method	Specification	Result
Characters	Ph. Eur.	White or pale yellow, hygroscopic powder or friable solid	Complies
Appearance (Solution)	Ph. Eur.	The preparation dissolves completely with gentle swirling within 10 min, giving a clear or slightly opalescent colourless or slightly yellow solution. The solution may show a few small flakes or particles after reconstitution. The filtered solution is clear or slightly opalescent.	Complies
Solubility	Ph. Eur.	≤ 600 s	160 s
Bacterial endotoxins	Ph. Eur.	Complies (< 0.03 E.U./I.U.)	Complies
Chloride	Potentiometric	90 - 140 mmol/L	108 mmol/L
Citrate	Enzymatic test	6 - 16 mmol/L	12 mmol/L
Factor VIII Potency	Ph. Eur.	400 - 600 I.U./vial	470 I.U./vial
Factor vWF potency	Ph. Eur.	N.A.	180 I.U./vial
Factor vWF:Ag	Immunochemical	N.A.	215 I.U./vial
Fibrinogen	Immunochemical	≤ 4.0 mg/vial	<1.4 mg/vial
Glycine	Kjeldhal	76 - 104 mg/vial	95 mg/vial
Haemagglutinins Anti-A1	Ph. Eur.	< 1:64	1:4
Haemagglutinins Anti-B	Ph. Eur.	< 1:64	1:2
Identity	Ph. Eur.	Complies	Complies
Osmolality	Ph. Eur.	≥ 240 mOsmol/kg	356 mOsmol/kg
pH	Ph. Eur.	6.5 - 7.5	7.0
Polisorbate 80	Spectrophotometric	≤ 100 ppm	12 ppm
Sodium	Atomic emission spectrophotometry	120 - 180 mmol/L	142 mmol/L
Specific activity	N.A.	N.A.	157 IU/mg
Sterility	Ph. Eur.	Sterile	Sterile
Total Proteins	Bradford	≤ 7.2 mg/vial	3.0 mg/vial
Tri(n-butyl)phosphate	Gascromatographyc	≤ 5 ppm	<1 ppm
vWF:Rco/FVIII:C	N.A.	≥ 0.25	0.38
Water	Ph. Eur.	≤ 3 %	2 %

Reference: 105115
CoA: 1013890-STD
Certificate No.: 194577 Date: 30/01/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452235				
Code:	1013890				
Production Date:	12-2022	**Validity Start Date:**	12-2022	**Expiry Date:**	11-2025
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Certified By: Sara Del Carlo
Quality Control Manager
Date: 19/01/2023 06:39:07

This is an electronic signature

KEDRION
BIOPHARMA

Certificate for medicinal product

EMOCLOT 500 IU/10 ML

Batch Number:	452235				
Code:	1013890				
Production Date:	12-2022	**Validity Start Date:**	12-2022	**Expiry Date:**	11-2025
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

The Human Plasma was collected from healthy donors according to European Guidelines, National Requirements and European Pharmacopoeia (Monograph 0853) with the aim of assuring the suitability of the individual donations. Every donation is tested and found non-reactive for:
- HBsAg, anti-HIV1/HIV2, anti-HCV.
- HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and Parvovirus B19-DNA by test NAT done by minipool testing. Units with a Parvovirus B19-DNA of elevated titer are excluded. The manufacturing plasma pools were tested and found to be non-reactive for HBsAg, anti-HIV1/HIV2 and by NAT for HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and tested for Parvovirus B -19 DNA. The manufacturing plasma pools used for the manufacture of the above batch were released from a European OMCL (Official Medicines Control Laboratory). I hereby certified that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and the requirements of the Marketing Authorization of the destination country/countries.

The Lot Is ..... APPROVED

Qualified Person: .....

Kedrion S.p.A.
Sara Del Carlo
Qualified Person
Bolognana Plant

Date: ..... 30 JAN 2023

Reference: 105115
CoA: 1013890-STD
Certificate No.: 194577 Date: 30/01/2023 From: Database: LIMS_PROD

Austrian
Federal Office for
Safety in Health Care
BASG

Dept. BAMA
Possingergasse 38, AT-1160 Wien
Dipl.Ing. (FH) Christoph Kefeder; e-mail: christoph.kefeder@ages.at
Phone: +43(0)5 0555 36331; Fax: +43(0)5 0555 36309
To: Kedrion S.p.A., IT

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE - Finished Product

Examined under Article 114 of Directives 2001/83/EC as amended by Directive 2004/27/EC (Medicinal Products derived from Human Blood or Plasma) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Trade name:	Emoclot 500 U.I./10 ml
International non-propriety name / Ph. Eur. name / common name:	Human Coagulation Factor VIII
Batch numbers appearing on package and other identification numbers associated with this batch:	452235
Type of container:	Glass Bottle
Total number of containers in this batch:	2739
Nominal dose per container:	500 I.U.
Date of start of period of validity:	17.12.2022
Date of expiry:	30.11.2025
Marketing authorisation number (member state / EU) issued by:	023564216 (Italy)
Name and address of manufacturer (site of Qualified Person signing summary protocol unless otherwise indicated):	Kedrion S.p.A. Via Provinciale Loc. Bolognana IT-55027 Gallicano (LU)
Name and address of marketing authorisation holder:	Kedrion S.p.A Loc. Ai Conti IT-55051 Castelvecchio Pascoli / Barga (Lucca)

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the EN/ISO 17025 standard.

This examination is based on the relevant EU OCABR guideline for this product.

All constituent plasma pools have been tested by an OMCL for virological markers.

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released.

Signed:	Ch. Kefeder
Name and Function of Signatory:	Dipl.Ing. (FH) Christoph Kefeder
Date of Issue:	19.01.2023
Release Certificate Number:	ZAT-230322

23003742

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452340				
Code:	1013890				
Production Date:	06-2023	**Validity Start Date:**	06-2023	**Expiry Date:**	05-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Test	Method	Specification	Result
Characters	Ph. Eur.	White or pale yellow, hygroscopic powder or friable solid	Complies
Appearance (Solution)	Ph. Eur.	The preparation dissolves completely with gentle swirling within 10 min, giving a clear or slightly opalescent colourless or slightly yellow solution. The solution may show a few small flakes or particles after reconstitution. The filtered solution is clear or slightly opalescent.	Complies
Solubility	Ph. Eur.	≤ 600 s	240 s
Bacterial endotoxins	Ph. Eur.	Complies (< 0.03 E.U./I.U.)	Complies
Chloride	Potentiometric	90 - 140 mmol/L	110 mmol/L
Citrate	Enzymatic test	6 - 16 mmol/L	11 mmol/L
Factor VIII Potency	Ph. Eur.	400 - 600 I.U./vial	528 I.U./vial
Factor vWF potency	Ph. Eur.	N.A.	162 I.U./vial
Factor vWF:Ag	Immunochemical	N.A.	216 I.U./vial
Fibrinogen	Immunochemical	≤ 4.0 mg/vial	<1.4 mg/vial
Glycine	Kjeldhal	76 - 104 mg/vial	91 mg/vial
Haemagglutinins Anti-A1	Ph. Eur.	< 1:64	1:4
Haemagglutinins Anti-B	Ph. Eur.	< 1:64	1:2
Identity	Ph. Eur.	Complies	Complies
Osmolality	Ph. Eur.	≥ 240 mOsmol/kg	356 mOsmol/kg
pH	Ph. Eur.	6.5 - 7.5	7.0
Polisorbate 80	Spectrophotometric	≤ 100 ppm	11 ppm
Sodium	Atomic emission spectrophotometry	120 - 180 mmol/L	141 mmol/L
Specific activity	N.A.	N.A.	132 IU/mg
Sterility	Ph. Eur.	Sterile	Sterile
Total Proteins	Bradford	≤ 7.2 mg/vial	4.0 mg/vial
Tri(n-butyl)phosphate	Gascromatographyc	≤ 5 ppm	<1 ppm
vWF:Rco/FVIII:C	N.A.	≥ 0.25	0.31
Water	Ph. Eur.	≤ 3 %	1 %

Reference: 114089
CoA: 1013890-STD
Certificate No.: 221244 Date: 04/09/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452340				
Code:	1013890				
Production Date:	06-2023	**Validity Start Date:**	06-2023	**Expiry Date:**	05-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Certified By: Ilaria Rossi
Deputy Quality Control Manager
Date: 05/07/2023 14:50:49

This is an electronic signature

KEDRION
BIOPHARMA

Certificate for medicinal product

EMOCLOT 500 IU/10 ML

Batch Number:	452340				
Code:	1013890				
Production Date:	06-2023	**Validity Start Date:**	06-2023	**Expiry Date:**	05-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

The Human Plasma was collected from healthy donors according to European Guidelines, National Requirements and European Pharmacopoeia (Monograph 0853) with the aim of assuring the suitability of the individual donations. Every donation is tested and found non-reactive for:
- HBsAg, anti-HIV1/HIV2, anti-HCV.
- HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and Parvovirus B19-DNA by test NAT done by minipool testing. Units with a Parvovirus B19-DNA of elevated titer are excluded. The manufacturing plasma pools were tested and found to be non-reactive for HBsAg, anti-HIV1/HIV2 and by NAT for HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and tested for Parvovirus B -19 DNA. The manufacturing plasma pools used for the manufacture of the above batch were released from a European OMCL (Official Medicines Control Laboratory). I hereby certified that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and the requirements of the Marketing Authorization of the destination country/countries.

APPROVED

The Lot Is .....

Qualified Person: .....

05 SEP 2023

Date: .....

Kedrion S.p.A.
Barbara Giulianetti
Qualified Person
Bolognana Plant

Austrian
Federal Office for
Safety in Health Care
BASG

Dept. BAMA
Possingergasse 38, AT-1160 Wien
Dipl.Ing. (FH) Christoph Kefeder; e-mail: christoph.kefeder@ages.at
Phone: +43(0)5 0555 36331; Fax: +43(0)5 0555 36309
To: Kedrion S.p.A., IT

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE - Finished Product

Examined under Article 114 of Directives 2001/83/EC as amended by Directive 2004/27/EC (Medicinal Products derived from Human Blood or Plasma) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Trade name:	Emoclot 500 U.I./10 ml
International non-propriety name / Ph. Eur. name / common name:	Human Coagulation Factor VIII
Batch numbers appearing on package and other identification numbers associated with this batch:	452340
Type of container:	Glass Bottle
Total number of containers in this batch:	3033
Nominal dose per container:	500 I.U.
Date of start of period of validity:	01.06.2023
Date of expiry:	31.05.2026
Marketing authorisation number (member state / EU) issued by:	023564216 (Italy)
Name and address of manufacturer (site of Qualified Person signing summary protocol unless otherwise indicated):	Kedrion S.p.A. Via Provinciale Loc. Bolognana IT-55027 Gallicano (LU)
Name and address of marketing authorisation holder:	Kedrion S.p.A Loc. Ai Conti IT-55051 Castelvecchio Pascoli / Barga (Lucca)

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the EN/ISO 17025 standard.

This examination is based on the relevant EU OCABR guideline for this product.

All constituent plasma pools have been tested by an OMCL for virological markers.

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released.

Signed:	Ch. Kefeder
Name and Function of Signatory:	Dipl.Ing. (FH) Christoph Kefeder
Date of Issue:	13.07.2023
Release Certificate Number:	ZAT-233430

23088059

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU 10 ML

Batch Number:	452320				
Code:	1013947				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Test	Method	Specification	Result
Characters	Ph. Eur.	White or pale yellow, hygroscopic powder or friable solid	Complies
Appearance (Solution)	Ph. Eur.	The preparation dissolves completely with gentle swirling within 10 min, giving a clear or slightly opalescent colourless or slightly yellow solution. The solution may show a few small flakes or particles after reconstitution. The filtered solution is clear or slightly opalescent.	Complies
Solubility	Ph. Eur.	≤ 600 s	200 s
Bacterial endotoxins	Ph. Eur.	Complies (< 0.03 E.U./I.U.)	Complies
Chloride	Potentiometric	90 - 140 mmol/L	111 mmol/L
Citrate	Enzymatic test	6 - 16 mmol/L	11 mmol/L
Factor VIII Potency	Ph. Eur.	400 - 600 I.U./vial	503 I.U./vial
Factor vWF potency	Ph. Eur.	N.A.	128 I.U./vial
Factor vWF:Ag	Immunochemical	N.A.	159 I.U./vial
Fibrinogen	Immunochemical	≤ 4.0 mg/vial	<1.4 mg/vial
Glycine	Kjeldhal	76 - 104 mg/vial	93 mg/vial
Haemagglutinins Anti-A1	Ph. Eur.	< 1:64	1:4
Haemagglutinins Anti-B	Ph. Eur.	< 1:64	1:2
Identity	Ph. Eur.	Complies	Complies
Osmolality	Ph. Eur.	≥ 240 mOsmol/kg	355 mOsmol/kg
pH	Ph. Eur.	6.5 - 7.5	6.9
Polisorbate 80	Spectrophotometric	≤ 100 ppm	13 ppm
Sodium	Atomic emission spectrophotometry	120 - 180 mmol/L	147 mmol/L
Specific activity	N.A.	N.A.	144 IU/mg
Sterility	Ph. Eur.	Sterile	Sterile
Total Proteins	Bradford	≤ 7.2 mg/vial	3.5 mg/vial
Tri(n-butyl)phosphate	Gascromatographyc	≤ 5 ppm	<1 ppm
vWF:Rco/FVIII:C	N.A.	≥ 0.25	0.25
Water	Ph. Eur.	≤ 3 %	2 %

Reference: 109396
CoA: 1013947-Egitto
Certificate No.: 216436 Date: 19/07/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU 10 ML

Batch Number:	452320				
Code:	1013947				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Certified By: Ilaria Rossi
Deputy Quality Control Manager
Date: 14/04/2023 16:43:34
This is an electronic signature

KEDRION
BIOPHARMA

Certificate for medicinal product

EMOCLOT 500 IU 10 ML

Batch Number:	452320				
Code:	1013947				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

The Human Plasma was collected from healthy donors according to European Guidelines, National Requirements and European Pharmacopoeia (Monograph 0853) with the aim of assuring the suitability of the individual donations. Every donation is tested and found non-reactive for:
- HBsAg, anti-HIV1/HIV2, anti-HCV.
- HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and Parvovirus B19-DNA by test NAT done by minipool testing. Units with a Parvovirus B19-DNA of elevated titer are excluded. The manufacturing plasma pools were tested and found to be non-reactive for HBsAg, anti-HIV1/HIV2 and by NAT for HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and tested for Parvovirus B -19 DNA. The manufacturing plasma pools used for the manufacture of the above batch were released from a European OMCL (Official Medicines Control Laboratory). I hereby certified that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and the requirements of the Marketing Authorization of the destination country/countries.

APPROVED

The Lot Is .....

Qualified Person: .....

Kedrion S.p.A.
Sara Del Carlo
Qualified Person
Bolognana Plant

20 JUL 2023

Date: .....

Reference: 109396
CoA: 1013947-Egitto
Certificate No.: 216436 Date: 19/07/2023 From: Database: LIMS_PROD

Austrian
Federal Office for
Safety in Health Care
BASG

Dept. BAMA
Possingergasse 38, AT-1160 Wien
Dipl.Ing. (FH) Christoph Kefeder; e-mail: christoph.kefeder@ages.at
Phone: +43(0)5 0555 36331; Fax: +43(0)5 0555 36309
To: Kedrion S.p.A., IT

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE - Finished Product

Examined under Article 114 of Directives 2001/83/EC as amended by Directive 2004/27/EC (Medicinal Products derived from Human Blood or Plasma) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Trade name:	Emoclot 500 U.I./10 ml
International non-propriety name / Ph. Eur. name / common name:	Human Coagulation Factor VIII
Batch numbers appearing on package and other identification numbers associated with this batch:	452320
Type of container:	Glass Bottle
Total number of containers in this batch:	2442
Nominal dose per container:	500 I.U.
Date of start of period of validity:	14.03.2023
Date of expiry:	28.02.2026
Marketing authorisation number (member state / EU) issued by:	023564216 (Italy)
Name and address of manufacturer (site of Qualified Person signing summary protocol unless otherwise indicated):	Kedrion S.p.A. Via Provinciale Loc. Bolognana IT-55027 Gallicano (LU)
Name and address of marketing authorisation holder:	Kedrion S.p.A Loc. Ai Conti IT-55051 Castelvecchio Pascoli / Barga (Lucca)

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the EN/ISO 17025 standard.

This examination is based on the relevant EU OCABR guideline for this product.

All constituent plasma pools have been tested by an OMCL for virological markers.

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released.

Signed:	Ch. Kefeder
Name and Function of Signatory:	Dipl.Ing. (FH) Christoph Kefeder
Date of Issue:	28.04.2023
Release Certificate Number:	ZAT-232114

23053237

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452216				
Code:	1013975				
Production Date:	10-2022	**Validity Start Date:**	10-2022	**Expiry Date:**	09-2025
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Test	Method	Specification	Result
Characters	Ph. Eur.	White or pale yellow, hygroscopic powder or friable solid	Complies
Appearance (Solution)	Ph. Eur.	The preparation dissolves completely with gentle swirling within 10 min, giving a clear or slightly opalescent colourless or slightly yellow solution. The solution may show a few small flakes or particles after reconstitution. The filtered solution is clear or slightly opalescent.	Complies
Solubility	Ph. Eur.	≤ 600 s	220 s
Bacterial endotoxins	Ph. Eur.	Complies (< 0.03 E.U./I.U.)	Complies
Chloride	Potentiometric	90 - 140 mmol/L	107 mmol/L
Citrate	Enzymatic test	6 - 16 mmol/L	11 mmol/L
Factor VIII Potency	Ph. Eur.	400 - 600 IU/bottle	459 IU/bottle
Factor vWF potency	Ph. Eur.	N.A.	125 IU/bottle
Factor vWF:Ag	Immunochemical	N.A.	130 IU/bottle
Fibrinogen	Immunochemical	≤ 4.0 mg/bottle	<1.4 mg/bottle
Glycine	Kjeldhal	76 - 104 mg/bottle	92 mg/bottle
Haemagglutinins Anti-A1	Ph. Eur.	< 1:64	1:8
Haemagglutinins Anti-B	Ph. Eur.	< 1:64	1:2
Identity	Ph. Eur.	Complies	Complies
Osmolality	Ph. Eur.	≥ 240 mOsmol/kg	350 mOsmol/kg
pH	Ph. Eur.	6.5 - 7.5	7.0
Polisorbate 80	Spectrophotometric	≤ 100 ppm	13 ppm
Sodium	Atomic emission spectrophotometry	120 - 180 mmol/L	141 mmol/L
Specific activity	N.A.	N.A.	200 IU/mg
Sterility	Ph. Eur.	Sterile	Sterile
Total Proteins	Bradford	≤ 7.2 mg/bottle	2.3 mg/bottle
Tri(n-butyl)phosphate	Gascromatographyc	≤ 5 ppm	<1 ppm
vWF:Rco/FVIII:C	N.A.	≥ 0.25	0.27
Water	Ph. Eur.	≤ 3 %	2 %

Reference: 101614
CoA: 1013975-STD (L)
Certificate No.: 189634 Date: 15/12/2022 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452216				
Code:	1013975				
Production Date:	10-2022	**Validity Start Date:**	10-2022	**Expiry Date:**	09-2025
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Certified By: Ilaria Rossi
Deputy Quality Control Manager
Date: 28/11/2022 14:24:33
This is an electronic signature

KEDRION
BIOPHARMA

Certificate for medicinal product

EMOCLOT 500 IU/10 ML

Batch Number:	452216				
Code:	1013975				
Production Date:	10-2022	**Validity Start Date:**	10-2022	**Expiry Date:**	09-2025
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

The Human Plasma was collected from healthy donors according to European Guidelines, National Requirements and European Pharmacopoeia (Monograph 0853) with the aim of assuring the suitability of the individual donations. Every donation is tested and found non-reactive for:
- HBsAg, anti-HIV1/HIV2, anti-HCV.
- HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and Parvovirus B19-DNA by test NAT done by minipool testing. Units with a Parvovirus B19-DNA of elevated titer are excluded. The manufacturing plasma pools were tested and found to be non-reactive for HBsAg, anti-HIV1/HIV2 and by NAT for HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and tested for Parvovirus B -19 DNA. The manufacturing plasma pools used for the manufacture of the above batch were released from a European OMCL (Official Medicines Control Laboratory). I hereby certified that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and the requirements of the Marketing Authorization of the destination country/countries.

APPROVED

The Lot Is .....

Qualified Person: .....

Kedrion S.p.A.
Barbara Giulianetti
Qualified Person
Bolognana Plant

Date: 16 DEC 2022

Reference: 101614
CoA: 1013975-STD (L)
Certificate No.: 189634 Date: 15/12/2022 From: Database: LIMS_PROD

CENTRO NAZIONALE
CONTROLLO
E VALUTAZIONE DEI FARMACI

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE - Finished Product
Examined under Article 114 of Directives 2001/83/EC as amended by Directive 2004/27/EC (Medicinal Products derived from Human Blood or Plasma) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

ISS Release Certificate number	362/EMO/22/BR
Date of issue:	29/11/2022

Trade name	Emoclot
International non-proprietary Name	Human Coagulation Factor VIII
Batch number	452216
Type of container	Glass bottle
Total number of containers in this batch	2671
Nominal dose(s) per container	500 IU/10mL
Date of start of period of validity	10/10/2022
Date of expiry	30/09/2025
Marketing authorisation number issued by	023564216 (Italy)
Name and address of manufacturer	Kedrion S.p.A. Via Provinciale, Loc. Bolognana, 55027 , Gallicano (LU) Italy
Name and address of marketing authorisation holder if different	Kedrion S.p.A. Loc. Ai Conti, 55051, Castelvecchio Pascoli, Barga (LU) Italy

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard. This examination is based on the relevant EU OCABR guideline for this product and the review of the manufacturer's protocol.

Each constituent plasma pool has been tested by the ISS (Italy) for virological markers.

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released.

Signed	Firmato digitalmente da **Isabella Sestili** CN = Isabella Sestili C = IT
Name and function of signatory	Dr. Sestili Isabella, on behalf of Dr. Cristiana Chelucci Acting Director of the National Centre for the Control and Evaluation of Medicines

Istituto Superiore di Sanità
National Centre for the Control and Evaluation of Medicines
CNCF

Viale Regina Elena 299,
00161 – Rome (I)
VAT 03657731000

Telephone: +39 06 4990 1
PEC: cncf@pec.iss.it
mail: ocabr-blood.cncf@iss.it

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452319				
Code:	1013976				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Test	Method	Specification	Result
Characters	Ph. Eur.	White or pale yellow, hygroscopic powder or friable solid	Complies
Appearance (Solution)	Ph. Eur.	The preparation dissolves completely with gentle swirling within 10 min, giving a clear or slightly opalescent colourless or slightly yellow solution. The solution may show a few small flakes or particles after reconstitution. The filtered solution is clear or slightly opalescent.	Complies
Solubility	Ph. Eur.	≤ 600 s	190 s
Bacterial endotoxins	Ph. Eur.	Complies (< 0.03 E.U./I.U.)	Complies
Chloride	Potentiometric	90 - 140 mmol/L	110 mmol/L
Citrate	Enzymatic test	6 - 16 mmol/L	13 mmol/L
Factor VIII Potency	Ph. Eur.	400 - 600 I.U./vial	474 I.U./vial
Factor vWF potency	Ph. Eur.	N.A.	131 I.U./vial
Factor vWF:Ag	Immunochemical	N.A.	165 I.U./vial
Fibrinogen	Immunochemical	≤ 4.0 mg/vial	<1.4 mg/vial
Glycine	Kjeldhal	76 - 104 mg/vial	93 mg/vial
Haemagglutinins Anti-A1	Ph. Eur.	< 1:64	1:4
Haemagglutinins Anti-B	Ph. Eur.	< 1:64	1:2
Identity	Ph. Eur.	Complies	Complies
Osmolality	Ph. Eur.	≥ 240 mOsmol/kg	357 mOsmol/kg
pH	Ph. Eur.	6.5 - 7.5	7.0
Polisorbate 80	Spectrophotometric	≤ 100 ppm	13 ppm
Sodium	Atomic emission spectrophotometry	120 - 180 mmol/L	146 mmol/L
Specific activity	N.A.	N.A.	169 IU/mg
Sterility	Ph. Eur.	Sterile	Sterile
Total Proteins	Bradford	≤ 7.2 mg/vial	2.8 mg/vial
Tri(n-butyl)phosphate	Gascromatographyc	≤ 5 ppm	<1 ppm
vWF:Rco/FVIII:C	N.A.	≥ 0.25	0.28
Water	Ph. Eur.	≤ 3 %	1 %

Reference: 109166
CoA: 1013976-STD (L)
Certificate No.: 221236 Date: 04/09/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452319				
Code:	1013976				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Certified By: Sara Del Carlo
Quality Control Manager
Date: 12/04/2023 18:27:32
This is an electronic signature

KEDRION
BIOPHARMA

Certificate for medicinal product

EMOCLOT 500 IU/10 ML

Batch Number:	452319				
Code:	1013976				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

The Human Plasma was collected from healthy donors according to European Guidelines, National Requirements and European Pharmacopoeia (Monograph 0853) with the aim of assuring the suitability of the individual donations. Every donation is tested and found non-reactive for:
- HBsAg, anti-HIV1/HIV2, anti-HCV.
- HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and Parvovirus B19-DNA by test NAT done by minipool testing. Units with a Parvovirus B19-DNA of elevated titer are excluded. The manufacturing plasma pools were tested and found to be non-reactive for HBsAg, anti-HIV1/HIV2 and by NAT for HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and tested for Parvovirus B -19 DNA. The manufacturing plasma pools used for the manufacture of the above batch were released from a European OMCL (Official Medicines Control Laboratory). I hereby certified that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and the requirements of the Marketing Authorization of the destination country/countries.

APPROVED

The Lot Is .....

Qualified Person: .....

Date: 05 SEP 2023

Kedrion S.p.A.
Barbara Giullianetti
Qualified Person
Bolognana Plant

Reference: 109166
CoA: 1013976-STD (L)
Certificate No.: 221236 Date: 04/09/2023 From: Database: LIMS_PROD

CENTRO NAZIONALE
CONTROLLO
E VALUTAZIONE DEI FARMACI

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE - Finished Product
Examined under Article 114 of Directives 2001/83/EC as amended by Directive 2004/27/EC (Medicinal Products derived from Human Blood or Plasma) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

ISS Release Certificate number	246/EMO/23/BR
Date of issue:	28/07/2023

Trade name	Emoclot
International non-proprietary Name	Human Coagulation Factor VIII
Batch number	452319
Type of container	Glass bottle
Total number of containers in this batch	2890
Nominal dose(s) per container	500 IU/10mL
Date of start of period of validity	08/03/2023
Date of expiry	28/02/2026
Marketing authorisation number issued by	023564216 (Italy)
Name and address of manufacturer	Kedrion S.p.A. Via Provinciale, Loc. Bolognana, 55027 , Gallicano (LU) Italy
Name and address of marketing authorisation holder if different	Kedrion S.p.A. Loc. Ai Conti, 55051, Castelvecchio Pascoli, Barga (LU) Italy

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the ISO/IEC 17025 standard. This examination is based on the relevant EU OCABR guideline for this product and the review of the manufacturer's protocol.

Each constituent plasma pool has been tested by the ISS (Italy) for virological markers.

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released.

Signed	Firmato digitalmente da **Giulio Pisani** CN = Giulio Pisani
Name and function of signatory	Dr. Giulio Pisani Director of the National Centre for the Control and Evaluation of Medicines

Istituto Superiore di Sanità
National Centre for the Control and Evaluation of Medicines
CNCF

Viale Regina Elena 299,
00161 – Rome (I)
VAT 03657731000

Telephone: +39 06 4990 1
PEC: cncf@pec.iss.it
mail: ocabr-blood.cncf@iss.it

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452323				
Code:	1013976				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Test	Method	Specification	Result
Characters	Ph. Eur.	White or pale yellow, hygroscopic powder or friable solid	Complies
Appearance (Solution)	Ph. Eur.	The preparation dissolves completely with gentle swirling within 10 min, giving a clear or slightly opalescent colourless or slightly yellow solution. The solution may show a few small flakes or particles after reconstitution. The filtered solution is clear or slightly opalescent.	Complies
Solubility	Ph. Eur.	≤ 600 s	220 s
Bacterial endotoxins	Ph. Eur.	Complies (< 0.03 E.U./I.U.)	Complies
Chloride	Potentiometric	90 - 140 mmol/L	110 mmol/L
Citrate	Enzymatic test	6 - 16 mmol/L	11 mmol/L
Factor VIII Potency	Ph. Eur.	400 - 600 I.U./vial	501 I.U./vial
Factor vWF potency	Ph. Eur.	N.A.	133 I.U./vial
Factor vWF:Ag	Immunochemical	N.A.	178 I.U./vial
Fibrinogen	Immunochemical	≤ 4.0 mg/vial	<1.4 mg/vial
Glycine	Kjeldhal	76 - 104 mg/vial	96 mg/vial
Haemagglutinins Anti-A1	Ph. Eur.	< 1:64	1:4
Haemagglutinins Anti-B	Ph. Eur.	< 1:64	1:2
Identity	Ph. Eur.	Complies	Complies
Osmolality	Ph. Eur.	≥ 240 mOsmol/kg	355 mOsmol/kg
pH	Ph. Eur.	6.5 - 7.5	7.0
Polisorbate 80	Spectrophotometric	≤ 100 ppm	14 ppm
Sodium	Atomic emission spectrophotometry	120 - 180 mmol/L	149 mmol/L
Specific activity	N.A.	N.A.	179 IU/mg
Sterility	Ph. Eur.	Sterile	Sterile
Total Proteins	Bradford	≤ 7.2 mg/vial	2.8 mg/vial
Tri(n-butyl)phosphate	Gascromatographyc	≤ 5 ppm	<1 ppm
vWF:Rco/FVIII:C	N.A.	≥ 0.25	0.27
Water	Ph. Eur.	≤ 3 %	1 %

Reference: 109917
CoA: 1013976-STD (L)
Certificate No.: 224524 Date: 25/09/2023 From: Database: LIMS_PROD

KEDRION
BIOPHARMA

Certificate of Analysis

EMOCLOT 500 IU/10 ML

Batch Number:	452323				
Code:	1013976				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

Certified By: Sara Del Carlo
Quality Control Manager
Date: 28/04/2023 09:25:58
This is an electronic signature

KEDRION
BIOPHARMA

Certificate for medicinal product

EMOCLOT 500 IU/10 ML

Batch Number:	452323				
Code:	1013976				
Production Date:	03-2023	**Validity Start Date:**	03-2023	**Expiry Date:**	02-2026
Pharmaceutical Form:	Powder and solvent for solution for infusion			**Volume of Solvent:**	10 mL
Storage Condition:	Store at +2 - +8°C (in a refrigerator), protect from light.				

The Human Plasma was collected from healthy donors according to European Guidelines, National Requirements and European Pharmacopoeia (Monograph 0853) with the aim of assuring the suitability of the individual donations. Every donation is tested and found non-reactive for:
- HBsAg, anti-HIV1/HIV2, anti-HCV.
- HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and Parvovirus B19-DNA by test NAT done by minipool testing. Units with a Parvovirus B19-DNA of elevated titer are excluded. The manufacturing plasma pools were tested and found to be non-reactive for HBsAg, anti-HIV1/HIV2 and by NAT for HCV-RNA, HIV-RNA, HBV-DNA, HAV-RNA and tested for Parvovirus B -19 DNA. The manufacturing plasma pools used for the manufacture of the above batch were released from a European OMCL (Official Medicines Control Laboratory). I hereby certified that all manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements and the requirements of the Marketing Authorization of the destination country/countries.

The Lot Is APPROVED

Qualified Person: .....

Kedrion S.p.A.
Sara Del Carlo
Qualified Person
Bolognana Plant

Date: 26 SEP 2023

Reference: 109917
CoA: 1013976-STD (L)
Certificate No.: 224524 Date: 25/09/2023 From: Database: LIMS_PROD

Austrian
Federal Office for
Safety in Health Care
BASG

Dept. BAMA
Possingergasse 38, AT-1160 Wien
Ing. Stephanie Eichmeir; e-mail: stephanie.eichmeir@ages.at
Phone: +43(0)5 0555 36334; Fax: +43(0)5 0555 36309
To: Kedrion S.p.A., IT

EU/EEA OFFICIAL CONTROL AUTHORITY BATCH RELEASE CERTIFICATE - Finished Product

Examined under Article 114 of Directives 2001/83/EC as amended by Directive 2004/27/EC (Medicinal Products derived from Human Blood or Plasma) and in accordance with the Administrative Procedure for Official Control Authority Batch Release.

Trade name:	Emoclot 500 U.I./10 ml
International non-propriety name / Ph. Eur. name / common name:	Human Coagulation Factor VIII
Batch numbers appearing on package and other identification numbers associated with this batch:	452323
Type of container:	Glass Bottle
Total number of containers in this batch:	2172
Nominal dose per container:	500 I.U.
Date of start of period of validity:	31.03.2023
Date of expiry:	28.02.2026
Marketing authorisation number (member state / EU) issued by:	023564216 (Italy)
Name and address of manufacturer (site of Qualified Person signing summary protocol unless otherwise indicated):	Kedrion S.p.A. Via Provinciale Loc. Bolognana IT-55027 Gallicano (LU)
Name and address of marketing authorisation holder:	Kedrion S.p.A Loc. Ai Conti IT-55051 Castelvecchio Pascoli / Barga (Lucca)

This batch has been examined using documented procedures which form part of a quality system which is in accordance with the EN/ISO 17025 standard.

This examination is based on the relevant EU OCABR guideline for this product.

All constituent plasma pools have been tested by an OMCL for virological markers.

This batch is in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monographs and the above marketing authorisation and is released.

Signed:	
Name and Function of Signatory:	Ing. Stephanie Eichmeir
Date of Issue:	11.08.2023
Release Certificate Number:	ZAT-233915

23104748

KEDRION
BIOPHARMA

BASG - Austrian Federal Office for Safety in Health Care
Head of Department Analytics of Biological Medicinal Products
attn. Dipl.-Ing. Heidemarie Schindl
Possingergasse 38
Vienna 1160

AUSTRIA

Bolognana 27. APR. 2023.

Batch Release EMOCLOT 500 I.U./10 ML **Batch no: 452320**

Dear Dipl.-Ing. Heidemarie Schindl,

We apply for an EU Batch Release of EMOCLOT 500 I.U./10 ML Batch no: 452320.

Please find enclosed the "Documents for Batch Release According to EEC Guidelines" second part for the Parallel Batch Release of the respective batch.

The samples have been sent to BASG - Austrian Federal Office for Safety in Health Care on April 19th, 2023.

If there are any further questions we are at your disposal at any time.

Yours sincerely

KEDRION S.p.A.
Factory of Bolognana - Lucca

Kedrion S.p.A.
Sara Del Carlo
Qualified Person
Bolognana Plant

Qualified Person
Contact details for Qualified Person: OCABR_OMCL@kedrion.com
Phone: +39 0583 767453 - Fax: +39 02 57763795

Enclosure

Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Abteilung BAMA
Possingergasse 38, 1160 Wien

ANTRAG AUF CHARGENFREIGABE / APPLICATION FOR BATCH RELEASE

An das BASG
Possingergasse 38
1160 Wien

☒ EC/EEA Official Control Authority Batch Release Certificate ☐ Additional Submission

☐ Nationales Chargenfreigabe Zertifikat

☐ Nationales Chargenfreigabe Zertifikat für KLINIKANFORDERUNG gem. § 8 AMG

☐ Nationales Chargenfreigabe Zertifikat für Export

Name und Adresse des Antragstellers / Name and Address of Applicant KEDRION S.p.A. Loc. Ai Conti, 55051 Castelvecchio Pascoli, Barga (Lucca) - ITALY	
Name und Adresse des Herstellers / Name and Address of Manufacturer KEDRION S.p.A. Via Provinciale - Frazione Bolognana, 55027 - Gallicano (LUCCA) - ITALY	**Name und Adresse des Zulassungsinhabers / Name and Address of MAH** KEDRION S.p.A. Loc. Ai Conti, 55051 Castelvecchio Pascoli, Barga (Lucca) - ITALY
Handelsname / Trade Name EMOCLOT 500 I.U./10 ML	**Arzneibuchbezeichnung / International Non-proprietary Name (INN)** Human Coagulation Factor VIII
Zulassungsnummer (bzw. -status) / Marketing Authorisation Number 023564216	**Zugelassen durch / MA issued by (EU member state or others)** ITALY
Lagertemperatur / Storage Temperature Store at +2°C - +8°C (in a refrigerator), in the original package and in the outer carton, protected from light.	**Art des Behälters / Type of Container** Glass Bottle
Chargennummer / Batch Number 452320	**Packungsgröße / Nominal Dose per Container** 500 I.U.
Herstellungsdatum / Manufacturing Date 14.03.2023	**Anzahl der Endbehälter / Number of Containers** 2.442
Beginn der Laufzeit / Date of Start of Period of Validity 14.03.2023	**Ablaufdatum / Expiry Date** 28.02.2026
Lösungsvolumen / Filling Volume 10,0 mL/vial	**Chargennummer des Lösungsmittels / Batch Number of Solvent** KA0822
Anzahl der mitgelieferten Endprodukte / Number of supplied Containers 1	**Anzahl der mitgelieferten Poolplasmen / Number of supplied Poolplasmas** N.A.

27 APR 2023
Qualified Person (signature, date)

Kedrion S.p.A.
Sara Del Carlo
Qualified Person
Bolognana Plant

KEDRION
BIOPHARMA

DOCUMENTS FOR BATCH RELEASE ACCORDING EEC GUIDELINES

(Council Directive 2001/83/EC formely 89/381/EEC, amended by Directive 2004/27/EC - 1 January 2006)

Name of the Medicinal Product:	Human Coagulation Factor VIII
Trade Name:	**EMOCLOT 500 I.U./10 ML**
Manufacturer:	KEDRION S.p.A. - Factory of Bolognana Via Provinciale - Frazione Bolognana, 55027 - Gallicano (LUCCA) - ITALY
Distributor and Registration Holder:	KEDRION S.p.A. Loc. Ai Conti, 55051 Castelvecchio Pascoli, Barga (Lucca) - ITALY
Marketing Authorization Number:	023564216
Batch-Number under which product was manufactured:	**8058714**
Batch Number for EU release:	**452320**
Filling date:	14/03/2023
Date of starting validity:	14/03/2023
Expiry Date:	28/02/2026
Number of containers produced:	2.442
Storage conditions:	Store at +2°C - +8°C (in a refrigerator), in the original package and in the outer carton, protected from light.

Reference to specifications: S.O.P. n° QSP-12-002 Rev. 18

POTENCY

Method: Chromogenic/Kinetic

Method principle: Activation of Factor X by activated Factor IX

Standard: HUMAN COAGULATION FACTOR VIII CONCENTRATE BRP (BATCH No. 5) Cod. H0920000

- calibration value declared: 9,9 I.U./bottle
- received from: COUNCIL OF EUROPE EUROPEAN PHARMACOPOEIA COMMISSION Biological Standardization
- material: Freeze Dried
- Storage temperature (°C): ≤ -20°C

Number of bottle tested: 2

Results of each assay (Potency and 95% fiducial limits)

- Bottle reconstituted with 10 ml of solvent

Date of assay	Bottle No.	Potency I.U./bottle
25/03/2023	1°	505
		508
25/03/2023	2°	496
		502

I.U./bottle and 95 % fiducial limits	
Mean potency =	503
Sd =	5,12
Significative level (Alpha=1-0,95) =	0,05
Sample size (n) =	4
CONFIDENCE =	6,03
95% Confidence interval =	503 ± 6,03
Manufacturer 95% confidence limits =	496,97 ÷ 509,03
Ph.Eur. Requirement: 95% confidence limits (P=0,95) to be between 80 - 120 % of estimate =	402,4 ÷ 603,6

Date of potency test: 25/03/2023

Method of combination: Aritmetical mean

Requirement: 400 ÷ 600 I.U./vial

Potency assigned to batch: 503 I.U./vial

Finished Product:

1. pH:

Method:	Potenziometer, glass electr., Ph. Eur.
Date:	23/03/2023
Requirements:	6,5 ÷ 7,5
Results:	6,9

2. Identity:

Method:	Ph. Eur.
Date:	25/03/2023
Requirements:	COMPLIES
Results:	Complies

Solubility:

Method:	Ph. Eur.
Date:	07/04/2023
Requirements:	The preparation dissolves completely with gentle swirling within 10 minutes. (≤ 600 s)
Results:	200 s

4. Visual inspection:

Method:	Ph. Eur.
Date:	07/04/2023
Requirements:	The preparation dissolves completely with gentle swirling within 10 min, giving a clear or slightly opalescent colourless or slightly yellow solution. The solution may show a few small flakes or particles after reconstitution. The filtered solution is clear or slightly opalescent.
esults:	Conform

5. Osmolality:

Method:	Cryoscopic, Ph. Eur.
Date:	27/03/2023
Requirements:	≥ 240 mOsmol/kg
Results:	355 mOsmol/kg

6. Total protein:

Method:	Bradford, Ph. Eur.
Date:	23/03/2023
Requirements:	≤ 7,2 mg/vial
Results:	3,5 mg/vial

7. Haemagglutinins (anti-A e anti-B):

Method:	Agglutination, Ph. Eur.
Date:	03/04/2023
Requirements:	Anti-A1 < 1/64 and Anti-B < 1/64
Results:	A1=1/4 - B=1/2

8. Water:

Method:	Karl fisher, Ph. Eur.
Date:	30/03/2023
Requirements:	≤ 3 %
Results:	2 %

9. Sterility:

Method:	Membrane filtration with the sterility-system with 2 media (according to Ph. Eur.) Number of containers: compliance with Ph. Eur. Incubation time: 14 days Incubation temp. +30°C ÷ +35°C (anaerobia, aerobia) +20°C ÷ +25°C (fungi)
Date:	07/04/2023
Requirements:	Sterile
Results:	Sterile

10. Bacterial Endotoxin:

Method:	Ph. Eur. (Kinetic LAL)
Date:	23/03/2023
Requirements:	Complies (< 0,030 EU/IU Factor VIII)
Results:	< 0,005 EU/IU Factor VIII

11. Potency Factor VIII:

Method:	Ph. Eur.
Date:	25/03/2023
Requirements:	400 ÷ 600 I.U./vial
Results:	503 I.U./vial (Against BRP Standard)

12. Specific activity:

Method:	N.A.
Date:	27/03/2023
Requirements:	N.A.
Results:	144 IU/mg

13. Fibrinogen:

Method:	Immunochemical
Date:	24/03/2023
Requirements:	≤ 4,0 mg/vial
Results:	< 1,4 mg/vial Factor VIII

14. Tween 80 (Polisorbate 80):

Method:	Spectrophotometric
Date:	23/03/2023
Requirements:	≤ 100 ppm
Results:	13 ppm

15. TnBP:

Method:	Gascromatographyc
Date:	28/03/2023
Requirements:	≤ 5 ppm
Results:	< 1 ppm

16. Sodium:

Method:	Atomic emission spectrophotometry
Date:	25/03/2023
Requirements:	120 ÷ 180 mmol/L
Results:	147 mmol/L

17. Chloride:

Method:	Potentiometric
Date:	23/03/2023
Requirements:	90 ÷ 140 mmol/L
Results:	111 mmol/L

18. Citrate:

Method:	Enzymatic test
Date:	24/03/2023
Requirements:	6 ÷ 16 mmol/L
Results:	11 mmol/L

19. Glycine:

Method:	Kjeldhal
Date:	03/04/2023
Requirements:	76 ÷ 104 mg/vial
Results:	93 mg/vial

20. Characters:

Method:	Ph. Eur.
Date:	07/04/2023
Requirements:	White or pale yellow, hygroscopic powder or friable solid
Results:	Conform

21. vWF:Rco/FVIII:C:

Method:	N.A.
Date:	02/04/2023
Requirements:	≥ 0,25
Results:	0,25

CERTIFICATION

I herewith certify that EMOCLOT 500 I.U./10 ML Batch No. 452320 was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirements. This includes that, for any materials derived from ruminants (bovine, ovine, caprine) used in the manufacture and/or formulation of the batch of product specified above, all measures have been taken to demonstrate compliance with Directive 2001/83/EC and amending Directives 2003/63/EC and 2004/27/EC.
In addition the OMCL performing OCABR has been notified of all relevant approved variations that have an impact on product specifications as described in the EU administrative procedure for OCABR.

Kedrion S.p.A.
Sara Del Carlo
Qualified Person
Bolognana Plant

Date: 27 APR 2023

Qualified Person

Reference to specifications: S.O.P. n° QSP-12-002 Rev. 18

KEDRION
BIOPHARMA

BASG - Austrian Federal Office for Safety in Health Care
Head of Department Analytics of Biological Medicinal Products
attn. Dipl.-Ing. Heidemarie Schindl
Possingergasse 38
Vienna 1160

AUSTRIA

Bolognana 14 APR 2023

Batch Release EMOCLOT 500 I.U./10 ML **Batch no: 452320**

Dear Dipl.-Ing. Heidemarie Schindl,

We apply for an EU Batch Release of EMOCLOT 500 I.U./10 ML Batch no: 452320.

Please find enclosed the "Documents for Batch Release According to EEC Guidelines" first part for the Parallel Batch Release of the respective batch.

The samples will be sent to BASG - Austrian Federal Office for Safety in Health Care on April 19th, 2023.

If there are any further questions we are at your disposal at any time.

Yours sincerely

KEDRION S.p.A.
Factory of Bolognana - Lucca

Kedrion S.p.A.
Barbara Giulianetti
Qualified Person
Bolognana Plant

Qualified Person
Contact details for Qualified Person: OCABR_OMCL@kedrion.com
Phone: +39 0583 767453 - Fax: +39 02 57763795

Enclosure

Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Abteilung BAMA
Possingergasse 38, 1160 Wien

ANTRAG AUF CHARGENFREIGABE / APPLICATION FOR BATCH RELEASE

An das BASG
Possingergasse 38
1160 Wien

☒ EC/EEA Official Control Authority Batch Release Certificate ☐ Additional Submission

☐ Nationales Chargenfreigabe Zertifikat

☐ Nationales Chargenfreigabe Zertifikat für KLINIKANFORDERUNG gem. § 8 AMG

☐ Nationales Chargenfreigabe Zertifikat für Export

Name und Adresse des Antragstellers / Name and Address of Applicant KEDRION S.p.A. Loc. Ai Conti, 55051 Castelvecchio Pascoli, Barga (Lucca) - ITALY	
Name und Adresse des Herstellers / Name and Address of Manufacturer KEDRION S.p.A. Via Provinciale - Frazione Bolognana, 55027 - Gallicano (LUCCA) - ITALY	**Name und Adresse des Zulassungsinhabers / Name and Address of MAH** KEDRION S.p.A. Loc. Ai Conti, 55051 Castelvecchio Pascoli, Barga (Lucca) - ITALY
Handelsname / Trade Name EMOCLOT 500 I.U./10 ML	**Arzneibuchbezeichnung / International Non-proprietary Name (INN)** Human Coagulation Factor VIII
Zulassungsnummer (bzw. -status) / Marketing Authorisation Number 023564216	**Zugelassen durch / MA issued by (EU member state or others)** ITALY
Lagertemperatur / Storage Temperature Store at +2°C - +8°C (in a refrigerator), in the original package and in the outer carton, protected from light.	**Art des Behälters / Type of Container** Glass Bottle
Chargennummer / Batch Number 452320	**Packungsgröße / Nominal Dose per Container** 500 I.U.
Herstellungsdatum / Manufacturing Date 14.03.2023	**Anzahl der Endbehälter / Number of Containers** N.A.
Beginn der Laufzeit / Date of Start of Period of Validity 14.03.2023	**Ablaufdatum / Expiry Date** 28.02.2026
Lösungsvolumen / Filling Volume 10,0 mL/vial	**Chargennummer des Lösungsmittels / Batch Number of Solvent** N.A.
Anzahl der mitgelieferten Endprodukte / Number of supplied Containers 1	**Anzahl der mitgelieferten Poolplasmen / Number of supplied Poolplasmas** N.A.

14 APR 2023

Qualified Person (signature, date)
Kedrion S.p.A.
Barbara Giulianetti
Qualified Person
Bolognana Plant

KEDRION
BIOPHARMA

DOCUMENTS FOR BATCH RELEASE ACCORDING EEC GUIDELINES

(Council Directive 2001/83/EC formely 89/381/EEC, amended by Directive 2004/27/EC - 1 January 2006)

Name of the Medicinal Product:	Human Coagulation Factor VIII
Trade Name:	**EMOCLOT 500 I.U./10 ML**
Manufacturer:	KEDRION S.p.A. - Factory of Bolognana Via Provinciale - Frazione Bolognana, 55027 - Gallicano (LUCCA) - ITALY
Distributor and Registration Holder:	KEDRION S.p.A. Loc. Ai Conti, 55051 Castelvecchio Pascoli, Barga (Lucca) - ITALY
Marketing Authorization Number:	023564216
Batch-Number under which product was manufactured:	**8058714**
Batch Number for EU release:	**452320**
Filling date:	14/03/2023
Date of starting validity:	14/03/2023
Expiry Date:	28/02/2026
Storage conditions:	Store at +2°C - +8°C (in a refrigerator), in the original package and in the outer carton, protected from light.

STARTING MATERIAL

Final Bulk N.: 8058714

Crio Paste crude N.	Quantity kg	Fractionation site	Plasma pool No.	Production date	Total kg	Number of donations	Suppliers [1] and Country of origin	Interval of collection
8ER3013122	24,180	HUMAN BioPlazma LLC Táncsics M. u. 80 2100 Gödöllö - HUNGARY	PER3013122	18/08/2022	2705,164	9.537	RCKIK LUBLIN - RCKIK RADOM - RCKIK WROCLAW (POLAND)	01/21 - 06/22
8ER3013232	13,530	HUMAN BioPlazma LLC Táncsics M. u. 80 2100 Gödöllö - HUNGARY	PER3013232	30/10/2022	2705,199	8.568	KREVNI CENTRUM - SUHL - LEIPZIG (CZECH REPUBLIC - GERMANY)	11/19 - 09/22
8ES3013132	31,070	HUMAN BioPlazma LLC Táncsics M. u. 80 2100 Gödöllö - HUNGARY	PES3013132	21/08/2022	2697,497	3.301	AMBER PLASMA - PLAZMA PLUS - LEIPZIG (CZECH REPUBLIC - GERMANY)	12/21 - 06/22
8ES3013142	19,590	HUMAN BioPlazma LLC Táncsics M. u. 80 2100 Gödöllö - HUNGARY	PES3013142	23/08/2022	2704,488	3.354	AMBER PLASMA - PL MEDICAL - PLAZMA PLUS - LEIPZIG - RUHR (CZECH REPUBLIC - GERMANY)	01/22 - 07/22
Totale :	**88,370**							

[1] In case of any problem, the necessary information concerning traceability will be provided by the company to the concerned OMCL(s).

Copy of n° 3 OCABR certificates of approval for plasma pools have been included:

1. PER3013122:.....ZAT-224190
2. PES3013132:.....ZAT-224191
3. PES3013142:.....ZAT-224191
4. PER3013232:.....ZAT-225640

The plasma pools were tested and found to be:
- Non-reactive for HBsAg, anti-HIV1/HIV2;
- Negative for HCV-RNA, HBV-DNA, HIV-RNA, HAV-RNA by NAT;
- Within the limit for Parvovirus-B19 DNA by NAT.

SOURCES OF PLASMA

The plasma has been collected from Centres that are indicated in the authorized Plasma Master File.

INDIVIDUAL DONATIONS

The human plasma used was collected from healthy donors according to European Guidelines, National Requirements and European Pharmacopoeia (Monograph 0853) with the aim of assuring the suitability of the individual donations.

This batch was manufactured from donations which were each tested and declared negative for:

- Hepatitis Bs Ag (HBsAg), Anti-HIV1/HIV2 and Anti-Hep CV (Anti-HCV)
- HAV RNA, HIV RNA, HBV DNA, HCV RNA and Parvovirus B19 DNA by test NAT done by minipool testing. Units with a Parvovirus B19 DNA of elevate titre are excluded.

PRODUCTION INFORMATION

In reference to the above mentioned medicinal speciality for which batch release is required we do hereby declare that:

- The fractionation plants (including those producing intermediate fractions);
- The final manufacturing locations;

are those provided in the approved dossier of marketing authorization licence.

INTERMEDIATE PRODUCT

Crio Paste crude Batch No. 8ER3013232

Manufacturer: HUMAN BioPlazma LLC
Táncsics M. u. 80
2100 Gödöllö - HUNGARY

Identification number: **8ER3013232**

Amount produced: **24,870 kg**

Date of manufacture: 31/10/2022

Storage time and temperature: 132 days at ≤ -20°C

Approved storage period in the Marketing Authorization: 2 years at ≤ -20°C

Crio Paste crude Batch No. 8ES3013142

Manufacturer: HUMAN BioPlazma LLC
Táncsics M. u. 80
2100 Gödöllö - HUNGARY

Identification number: **8ES3013142**

Amount produced: **37,960 kg**

Date of manufacture: 24/08/2022

Storage time and temperature: 200 days at ≤ -20°C

Approved storage period in the Marketing Authorization: 2 years at ≤ -20°C

Crio Paste crude Batch No. 8ES3013132

Manufacturer: HUMAN BioPlazma LLC
Táncsics M. u. 80
2100 Gödöllö - HUNGARY

Identification number: **8ES3013132**

Amount produced: **39,640 kg**

Date of manufacture: 22/08/2022

Storage time and temperature: 202 days at ≤ -20°C

Approved storage period in the Marketing Authorization: 2 years at ≤ -20°C

Crio Paste crude Batch No. 8ER3013122

Manufacturer: HUMAN BioPlazma LLC
Táncsics M. u. 80
2100 Gödöllö - HUNGARY

Identification number: **8ER3013122**

Amount produced: **24,180 kg**

Date of manufacture: 19/08/2022

Storage time and temperature: 205 days at ≤ -20°C

Approved storage period in the Marketing Authorization: 2 years at ≤ -20°C

PREPARATION OF FINAL BULK

INGREDIENTS	Solution mother batch No.	QUANTITY (kg)	PRODUCTION DATE
Concentrate solution	8058714	17,90	14/03/2023
Buffer		8,10	14/03/2023
	BATCH No.	**QUANTITY (g)**	
Sodium citrate	0000137196	75,400	14/03/2023
Sodium Chloride	0000145054	171,600	14/03/2023
Glycine	0000143209	228,800	14/03/2023

The production has been carried out according to the procedure approved by the National Authority during the registration phase.

No. of recipient of final bulk Solution mother batch No.: 8058714	Quantity (kg)
SER-222	26,00

FINISH PRODUCT

Preparation date: 12/03/2023

Filling date: 14/03/2023

No. of recipient of final bulk: SER-222

Type of container: ..... Glass bottle

Date of starting validity: 14/03/2023

Expiry date: 28/02/2026

Marketing authorization number: 023564216

Issued by: ..... A.I.FA. - AGENZIA ITALIANA DEL FARMACO - Italy

COMPOSITION	**QUANTITY**
Factor VIII	500 I.U./bottle
Tribasic sodium citrate	29,4 mg/bottle
Sodium chloride	66,0 mg/bottle
Glycine	90,0 mg/bottle
Calcium chloride	1,47 mg/bottle
Recostitution volume	10 ml

VIRAL INACTIVATION

The Batch N° 452320 has been subjected to a double step of viral inactivation treatment by the following process (in compliance with approved dossier):

Preparation of solvent/detergent mixture of Tween 80 and TnBP is prepared as follows: W.F.I. is heated and the calculated and weighed amount of Tween 80, to give a final concentration of 1,0 % w/v in the protein mixture, is added and dissolved with stirring. Then the calculated and weighed amount of TnBP, to give a final concentration of 0,3% w/v is added and the solution cooled with stirring to + 25°C ÷ + 26°C.

The amounts of the reagents are calculated and their weight is checked by two different operators. Both operators have to confirm the addition of these reagents by signature. The weight of the product before and after addition of the S.D. reagents is recorded.

The factor VIII solution is warmed to + 25°C ÷ + 26°C and, under stirring, the solvent detergent mixture is added slowly for a time of 15 ÷ 30 minutes.

At the end of the addition the solution is stirred at + 25°C ÷ + 26°C for at least 30 minutes in non V.I. area.

The factor VIII solution is transferred into the tank located in the post-virus inactivation area through an appropriate tube laying in the opening designed for this purpose between the two areas.

The solution is maintained under stirring at + 25°C ÷ + 26°C for not less than 8 hours.

After freeze-drying a second virus inactivation step is performed by heat treatment in a steam autoclave at 99,5° C ± 1,0°C for not less than 30 minutes.

The documentation of the two inactivation treatments has been controlled from Q.A. department and found in compliance with the mentioned specifications.

POTENCY

Method: Chromogenic/Kinetic

Method principle: Activation of Factor X by activated Factor IX

Standard: HUMAN COAGULATION FACTOR VIII CONCENTRATE BRP (BATCH No. 5) Cod. H0920000

- calibration value declared: 9,9 I.U./bottle
- received from: COUNCIL OF EUROPE EUROPEAN PHARMACOPOEIA COMMISSION Biological Standardization
- material: Freeze Dried
- Storage temperature (°C): ≤ -20°C

Number of bottle tested: 2

Results of each assay (Potency and 95% fiducial limits)

- Bottle reconstituted with 10 ml of solvent

Date of assay	Bottle No.	Potency I.U./bottle
25/03/2023	1°	505 508
25/03/2023	2°	496 502

I.U./bottle and 95 % fiducial limits	
Mean potency =	503
Sd =	5,12
Significative level (Alpha=1-0,95) =	0,05
Sample size (n) =	4
CONFIDENCE =	6,03
95% Confidence interval =	503 ± 6,03
Manufacturer 95% confidence limits =	496,97 ÷ 509,03
Ph.Eur. Requirement: 95% confidence limits (P=0,95) to be between 80 - 120 % of estimate =	402,4 ÷ 603,6

Date of potency test: 25/03/2023

Method of combination: Aritmetical mean

Requirement: 400 ÷ 600 I.U./vial

Potency assigned to batch: 503 I.U./vial

CERTIFICATION

I herewith certify that EMOCLOT 500 I.U./10 ML Batch No. 452320 was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirements. This includes that, for any materials derived from ruminants (bovine, ovine, caprine) used in the manufacture and/or formulation of the batch of product specified above, all measures have been taken to demonstrate compliance with Directive 2001/83/EC and amending Directives 2003/63/EC and 2004/27/EC.
In addition the OMCL performing OCABR has been notified of all relevant approved variations that have an impact on product specifications as described in the EU administrative procedure for OCABR.

Date: 14 APR 2023

B Giulianetti

Kedrion S.p.A.
Barbara Giulianetti Qualified Person
Qualified Person
Bolognana Plant

Reference to specifications: S.O.P. n° QSP-12-002 Rev. 18

Austrian
Federal Office for
Safety in Health Care
BASG

Dept. BAMA
Possingergasse 38, AT-1160 Wien
Dr. Dieter Pullirsch; e-mail: dieter.pullirsch@ages.at
Phone: +43(0)5 0555 36361; Fax: +43(0)5 0555 36309

EU/EEA CERTIFICATE OF APPROVAL FOR PLASMA POOLS FOR USE IN THE MANUFACTURE OF MEDICINAL PRODUCTS

Examined in the context of Official Control Authority Batch Release of medicinal products derived from human blood or plasma in application of Article 114 of Directive 2001/83/EC and amended by Directive 2004/27/EC.

Name and address of manufacturer of plasma pools (site of Qualified Person signing summary protocol unless otherwise indicated):

HUMAN BioPlazma Kft.
Tancsics Mihaly ut 80
2100 Gödöllö
Ungarn

sample No:	Code numbers of plasma pools:	Date of manufacture	Volume of pools (l):	Country of origin	PMF reference (+certification):
22101231	PER3013122	18.08.2022	2636,612	PL	EMEA/H/PMF/000012/07/IB/040

These plasma pools have been examined using documented procedures, which form part of a quality system which is in accordance with the EN ISO/IEC 17025 standard. This examination is based on the current EU OCABR guideline 'Official Control Authority Protocol for Approval of Plasma Pools': review of the plasma pool protocol and the following testing: The samples of these plasma pools (received: 23.08.2022) have been tested and found negative for the following virological markers: anti HIV 1+2 (EIA), HBsAg (EIA) and HCV RNA (NAT).

These plasma pools are in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monograph(s) and are approved.

QUALITY ASSURANCE DEPARTMENT
If this is green, it is an approved copy
Date 13/09/23 Signature

Signed:	
Name and Function of Signatory:	Dr. Dieter Pullirsch
Date of Issue:	13.09.2022
Release Certificate Number:	ZAT-224190

Austrian
Federal Office for
Safety in Health Care
BASG

Dept. BAMA
Possingergasse 38, AT-1160 Wien
Dr. Dieter Pullirsch; e-mail: dieter.pullirsch@ages.at
Phone: +43(0)5 0555 36361; Fax: +43(0)5 0555 36309

EU/EEA CERTIFICATE OF APPROVAL FOR PLASMA POOLS FOR USE IN THE MANUFACTURE OF MEDICINAL PRODUCTS

Examined in the context of Official Control Authority Batch Release of medicinal products derived from human blood or plasma in application of Article 114 of Directive 2001/83/EC and amended by Directive 2004/27/EC.

Name and address of manufacturer of plasma pools (site of Qualified Person signing summary protocol unless otherwise indicated):

HUMAN BioPlazma Kft.
Tancsics Mihaly ut 80
2100 Gödöllö
Ungarn

sample No:	Code numbers of plasma pools:	Date of manufacture	Volume of pools (l):	Country of origin	PMF reference (+certification):
22104095	PES3013132	21.08.2022	2629,139	CZ,GER	EMEA/H/PMF/000012/07/IB/040
22104097	PES3013142	23.08.2022	2635,953	CZ,GER	EMEA/H/PMF/000012/07/IB/040

These plasma pools have been examined using documented procedures, which form part of a quality system which is in accordance with the EN ISO/IEC 17025 standard. This examination is based on the current EU OCABR guideline 'Official Control Authority Protocol for Approval of Plasma Pools': review of the plasma pool protocol and the following testing: The samples of these plasma pools (received: 30.08.2022) have been tested and found negative for the following virological markers: anti HIV 1+2 (EIA), HBsAg (EIA) and HCV RNA (NAT).

These plasma pools are in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monograph(s) and are approved.

QUALITY ASSURANCE DEPARTMENT
If this is green, it is an approved copy
Date 03/09/23 Signature

Signed:	
Name and Function of Signatory:	Dr. Dieter Pullirsch
Date of Issue:	13.09.2022
Release Certificate Number:	ZAT-224191

Austrian
Federal Office for
Safety in Health Care
BASG

Dept. BAMA
Possingergasse 38, AT-1160 Wien
Dipl.Ing. (FH) Christoph Kefeder; e-mail: christoph.kefeder@ages.at
Phone: +43(0)5 0555 36331; Fax: +43(0)5 0555 36309

EU/EEA CERTIFICATE OF APPROVAL FOR PLASMA POOLS FOR USE IN THE MANUFACTURE OF MEDICINAL PRODUCTS

Examined in the context of Official Control Authority Batch Release of medicinal products derived from human blood or plasma in application of Article 114 of Directive 2001/83/EC and amended by Directive 2004/27/EC.

Name and address of manufacturer of plasma pools (site of Qualified Person signing summary protocol unless otherwise indicated):

HUMAN BioPlazma Kft.
Tancsics Mihaly ut 80
2100 Gödöllö
Ungarn

sample No:	Code numbers of plasma pools:	Date of manufacture	Volume of pools (l):	Country of origin	PMF reference (+certification):
22134404	PER3013232	30.10.2022	2636.646	CZK, GER	EMEA/H/PMF/000012/07/IB/040
22134406	PES3013252	03.11.2022	2635.766	CZK, GER	EMEA/H/PMF/000012/07/IB/040
22134405	PFM3013242	01.11.2022	1750.939	France	A-RA-CD-002-18

These plasma pools have been examined using documented procedures, which form part of a quality system which is in accordance with the EN ISO/IEC 17025 standard. This examination is based on the current EU OCABR guideline 'Official Control Authority Protocol for Approval of Plasma Pools': review of the plasma pool protocol and the following testing: The samples of these plasma pools (received: 08.11.2022) have been tested and found negative for the following virological markers: anti HIV 1+2 (EIA), HBsAg (EIA) and HCV RNA (NAT).

These plasma pools are in compliance with the approved specifications laid down in the relevant European Pharmacopoeia monograph(s) and are approved.

QUALITY ASSURANCE DEPARTMENT
If this is green, it is an approved copy
Date 05/04/23 Signature Cseuplc

Signed:	Ch. Kefeder
Name and Function of Signatory:	Dipl.Ing. (FH) Christoph Kefeder
Date of Issue:	02.12.2022
Release Certificate Number:	ZAT-225640

KEDRION
BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000034042*

CERTIFICATE OF ANALYSIS

N° 20220607152422

W.F.I. Solvent 10 ml

Batch Number
KA0822

Production Date
05/2022

Expiry Date
04/2027

Storage Temperature : Store at a temperature not higher than 25°C, protect from light. Do not freeze.

Tests	Methods	Requirements	Results
Appearance	Ph. Eur.	Clear, colourless liquid	Complies
Acidity/Alkalinity	Ph. Eur.	< =0,1 ml NaOH 0,01N/20 ml O < =0,15 ml HCl 0,01N/20 ml	Complies
Oxidisable Substances	Ph. Eur.	< 0,4 ml KMnO4 0,1N/100 ml The solution remains faintly pink	Complies
Chlorides (p.p.m.)	Ph. Eur.	< =0,5	< 0,5
Sterility	Ph. Eur.	Sterile	Sterile
Bacterial Endotoxin (E.U./ml)	Ph. Eur.	< 0,25	< 0,005
Nitrates (p.p.m.)	Ph. Eur.	< =0,2	< 0,2
Sulfates	Ph. Eur.	Absent/10ml	Absent
Ammonium (p.p.m)	Ph. Eur.	< =0,6	< 0,6
Calcium and Magnesium	Ph. Eur.	< =0,5 ml sodium edetate 0,01M/100 ml	Complies

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale
Data 07/06/22 Firma

Release O.M.C.L. N°: N.A. Date: N.A.
The Batch Is: APPROVED

Quality Control Manager : ..... **Date :** 07/06/2022

Qualified Person : Francesca De Rose ..... **Date :** 07/06/2022

KEDRION
BIOPHARMA

Material Code: 0006103761 *Inspection Lot: 030000034042*

CERTIFICATE OF ANALYSIS

N° 20220607152422

W.F.I. Solvent 10 ml

Batch Number: KA0822

Production Date: 05/2022

Expiry Date: 04/2027

Storage Temperature : Store at a temperature not higher than 25°C, protect from light. Do not freeze.

Tests	Methods	Requirements	Results
Particulate contamination (> = 10 µm): Sub-visible particles (Particles/container)	Ph. Eur.	< =6000	21
Particulate contamination (> = 25 µm): Sub-visible particles (Particles/container)	Ph. Eur.	< =600	1
Residue on evaporation (%)	Ph. Eur.	< =0,004	0,002
Conductivity (µS/cm)	Ph. Eur.	< =25	2
Extractable volume (ml)	Ph. Eur.	> =10,0	10,0

KEDRION S.p.A.
Quality Assurance
Copia conforme all'originale
Data 28/06/22 Firma ....

Release O.M.C.L. N°: N.A. Date: N.A.
The Batch Is: APPROVED

Quality Control Manager : ..... Date : 07/06/2022

Qualified Person : ..... Date : 06/06/2022