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3EC International a. s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2024-MDR/QS-022

UNIMED PHARMA spol. s r.o.
Orieškova 11, 821 05 Bratislava, Slovak Republic
SRN č.: SK-MF-000003111

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of medical device:

Eye drops, solution & Trypan blue sterile solution
Models / variants: Annex I
Intended purpose: Annex II
MD class IIb
(detailed list is stated in the annex(es) if applicable)

meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: **N/A**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the MD Technical Documentation Assessment Report No. MDR287_2023 from 15.02.2024, MD Clinical Evaluation Report No. MDR287_2023 from 15.02.2024 and MD Audit Report No. SK-0297-24 from 03.02.2025. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. For the placing on the market of the MDs which this certificate covers, the EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **10.02.2025**
Valid until: **22.02.2029**
First issue: **22.02.2024**
Revision: **01**
History: **Annex III**

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, **10.02.2025**

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ANNEX I TO EU QUALITY ASSURANCE CERTIFICATE No. 2024-MDR/QS-022

issued for the company

UNIMED PHARMA spol. s r.o.
Orieškova 11, 821 05 Bratislava, Slovak Republic

List of medical devices covered by the EU Quality Assurance Certificate:

MD type	Trade name	Alternative trade name	Variants
Eye drops, solution	OCU*flash*® eye drops, solution	-	1 x 10 ml, 2 x 10 ml
	OCU*flash*® *blue* eye drops, solution	-	**1 x 10 ml**
	OCU*hyl* C® eye drops, solution	-	**1 x 10 ml**
	SENSIVIT® eye drops, solution	-	**1 x 10 ml**
	Potassium-U eye drops, solution	**CATAROFT eye drops, solution**	**1 x 10 ml**
	Potassium-U preservative free, eye drops, solution	**CATAROFT FREE eye drops, solution**	**1 x 10 ml**
	SeptoZINC® eye drops, solution	-	**1 x 10 ml**
	UNI*tears*® preservative free eye drops, solution	-	**1 x 10 ml**
	HYPROMELOZA-P® eye drops, solution	-	**1 x 10 ml**
Trypan blue sterile solution	**CONTRAST BLUE® 0.1% trypan blue sterile solution**	-	**1 x 0.5 ml**

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Intended purpose of medical devices covered by the EU Quality Assurance Certificate:

OCU*flash*® eye drops, solution	OCU*flash* eye drops, solution is intended to flush irritating particles, chemicals and foreign bodies from the eye, to flush the eye in case ocular surface injuries, and to drip into the eye when exposed to environmental factors (e.g. pollution, computer use, air conditioning) as prevention and complementary symptomatic treatment of non-infectious inflammation of the eyelids, conjunctiva and chronical conjunctiva infections.
OCU*flash*® *blue* eye drops, solution	**OCU*flash blue* eye drops, solution is intended to flush irritating particles, chemicals and foreign bodies from the eye, to flush the eye in case ocular surface injuries, and to drip into the eye when exposed to environmental factors (e.g. pollution, computer use, air conditioning) as prevention and complementary symptomatic treatment of non-infectious inflammation of the eyelids, conjunctiva and chronical conjunctiva infections.**
OCU*hyl* C® eye drops, solution	**OCU*hyl* C eye drops, solution is intended for an eye hydration, to create a temporary protective film on the eye cornea within insufficient tear formation, to improve tear film stability and quality thus moisturizing and protecting the eye surface. In conditions associated with dry eye symptoms.**
SENSIVIT® eye drops, solution	**SENSIVIT eye drops, solution is intended for ocular use to create a temporary protective film on the eye cornea within insufficient tear formation to improve tear stability and quality and moisturize and protect the surface of eye.**
Potassium-U / CATAROFT eye drops, solution	**Potassium-U eye drops, solution is intended to be dropped into eye or to flush the eye of irritating particles to reduce inflammation, discomfort or risk of infection for prevention and supportive treatment of resorption processes for various eye conditions (e.g. exudates, hemorrhage, degenerative changes in corpus vitreum, cataracts of various etiologies) and supportive treatment of dry eye.**
Potassium-U preservative free / CATAROFT FREE eye drops, solution	**Potassium-U preservative free eye drops, solution is intended to be dropped into eye or to flush the eye of irritating particles to reduce inflammation, discomfort or risk of infection for prevention and supportive treatment of resorption processes for various eye conditions (e.g. exudates, hemorrhage, degenerative changes in corpus vitreum, cataracts of various etiologies) and supportive treatment of dry eye.**

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Intended purpose of medical devices covered by the EU Quality Assurance Certificate:

SeptoZINC® eye drops, solution	SeptoZINC eye drops, solution is intended to be used to flush the eye of irritating particulates and/or chemicals and to drip into the eye when exposed to environmental factors (e.g. pollution, computer use, air conditioning). To help prevent eye infections and as a supportive treatment of conjunctiva and chronic conjunctiva infections.
UNI*tears*® preservative free eye drops, solution	UNI*tears* preservative free eye drops, solution is intended to create a temporary protective film on the eye cornea within insufficient tear formation thus moisturizing and protecting the eye surface in conditions associated with dry eye symptoms and in patients with small corneal erosions.
HYPROMELOZA-P® eye drops, solution	HYPROMELOZA-P eye drops, solution is intended to create a temporary protective film on the eye cornea within insufficient tear formation thus moisturizing and protecting the eye surface in conditions associated with dry eye symptoms and in patients with small corneal erosions.
CONTRAST BLUE® 0.1% trypan blue sterile solution	CONTRAST BLUE 0.1% trypan blue sterile solution is used to stain connective eye tissue during ophthalmic surgery (e.g., phacoemulsification) and to enhance the visibility of intraocular structures (e.g., anterior lens capsule).

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ANNEX III TO EU QUALITY ASSURANCE CERTIFICATE No. 2024-MDR/QS-022

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UNIMED PHARMA spol. s r.o.

Oriešková 11, 821 05 Bratislava, Slovak Republic

Certificate history:

Revision	EU QA Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2024-MDR/QS-022	22.02.2024	MDR287_2023	Initially granted certification
01	**2024-MDR/QS-022**	**10.02.2025**	**MDR288_2023, MDR289_2023, MDR290_2023, MDR291_2023, MDR292_2023, MDR293_2023, MDR294_2023, MDR295_2023, MDR297_2023**	**Scope extension**

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