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.
Oriešková 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:

OCUflash® eye drops, solution
Models / variants: see Annex I
Intended purpose: see 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-0297-23 from 15.02.2024. 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. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

Valid from: **22.02.2024**
Valid until: **22.02.2029**
First issue: **22.02.2024**
Revision: **00**
History: **see Annex III**

3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, **22.02.2024**

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

issued for the company

UNIMED PHARMA spol. s r.o.

Oriešková 11, 821 05 Bratislava, Slovak Republic

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

MD type	Trade names	Models / variants
OCUflash® eye drops, solution	**OCUflash®**	1 x 10 ml
	OCUflash®	2 x 10 ml

Notified body
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NB 2265
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Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 22.02.2024
Valid until 22.02.2029

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

issued for the company

UNIMED PHARMA spol. s r.o.

Oriešková 11, 821 05 Bratislava, Slovak Republic

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

OCUflash® 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.

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 22.02.2024
Valid until 22.02.2029

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

issued for the company

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

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 22.02.2024
Valid until 22.02.2029