

in accordance with § 23 of Law No. 56/2018 on Technical Requirements for Products and on Conformity Assessment and on amendments to certain laws, as amended,

and with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC as amended (MDR).

UNIMED PHARMA, spol. s r.o., Oriškova 11, 821 05 Bratislava, Slovak republic
single registration number (SRN): SK-MF-000003111

Medical device type:	Sterile solution
Trade name of medical device:	CONTRAST BLUE® 0.1% trypan blue sterile solution
Variant:	1 × 0,5 ml
Basic UDI-DI:	8588009045CONTRASTBLUE98
Risk class of the Medical Device:	IIB, according to the Rule 21 of the EU Medical Device Regulation (MDR) 2017/745, Annex VIII
Intended purpose:	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).
Used procedure of conformity assessment:	Procedure of conformity assessment according to Regulation (EU) 2017/745 on medical devices, Annex IX Conformity assessment based on a quality management system and on assessment of technical documentation
Applied CS:	N/A
Name and number of Notified body (NB):	3EC International a.s. NB: 2265
Certificates issued:	Certificate: 2024-MDR/QS-022/A, revision 02 Issued: 11.12.2025 Expires: 22.02.2029


We issue the EU declaration of conformity under the sole responsibility of the manufacturer UNIMED PHARMA, spol. s r.o. and declare that the above-mentioned medical device is in accordance with the conformity assessment of the quality management system pursuant to Article 52 (4), the technical documentation pursuant to Annex IX and meets the general safety and performance requirements pursuant to Annex I of Regulation (EU) 2017/745 the European Parliament and of the Council of 5 April 2017 on medical devices and the device is in conformity with this Regulation. This medical device is marked with CE 2265.

The EU declaration of conformity was signed by the person responsible for regulatory compliance for and on behalf of the manufacturer UNIMED PHARMA, spol. s r.o.

In Bratislava, date: 2026-01-07
(Date and place of issue of the declaration)

Name and function of the responsible person
representing the manufacturer:

PharmDr. Vladimír Jančuš
PRRC



Signature of the responsible person
representing the manufacturer
Company stamp

