

EU Declaration of Conformity
Laser Silicone Ocular Shield- Sterile

Template Document Ref.:	QR-237	Template Rev No:	01	Template CC No:	441
D of C Ref No:	DOC-EUMDRS-19 Rev 01			D of C CC No:	441

Medasil Surgical Limited hereby declare the devices (Laser Silicone Ocular Shield-Sterile) listed in the attached Appendix 1 to this declaration meet the provisions of the Medical Device Regulation (EU) 2017/745 (MDR), for medical devices. Supporting Documentation is retained at the premises of the manufacturer. The EU Declaration of conformity with certificate number (GB24/00000131), is issued under the sole responsibility of Medasil Surgical Limited. Appendix 2 to this declaration provides a list of applicable common specifications/standards applied.

Manufacturer/Trade Name

Medasil Surgical Limited; Address: Medasil House, Hunslet Road, Leeds LS10 1AU, UK
SRN: 000009549.

**Notified Body**

SGS Belgium NV; Address: SGS House, Noorderlaan 87-2030 Antwerpen (1639)

Authorised Representative

European Healthcare and Device Solutions (Ireland) Ltd (EHDSL)
Address: Straton House, Bishopstown Road, Cork, Ireland, T12 Y9TC.
Tel: +353 (86)2280846; Website www.europeandevicessolutions.eu
SRN: 000003999.

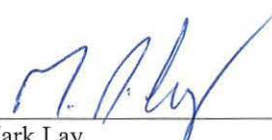
Conformity Assessment Route	Class	Rule
ANNEX IX	Is	5

Signed for and on behalf of Medasil Surgical Limited:


Naseem Daji
QA/RA Director
Medasil Surgical Limited

Date: 15 OCT 2024

Place: LEEDS / UK.


Mark Lay
Technical Director
Medasil Surgical Limited

Date: 16 OCT 2024

Place: LEEDS / UK

50 Years
1974-2024



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Product Code	GTIN UDI-DI	Basic UDI-DI	Product Name and Description
510-1101-2204	05060465562586	506046556510-11BW	Laserguard Silicone Ocular Shield Yellow OD 22mm, Units of 1, Sterile.
510-1125-2204	05060465562593		Laserguard Silicone Ocular Shield Yellow OD 22mm, Units of 1, Box of 25, Sterile.
510-1101-2205	05060465562609		Laserguard Silicone Ocular Shield Red OD 22mm, Units of 1, Sterile.
510-1125-2205	05060465562616		Laserguard Silicone Ocular Shield Red OD 22mm, Units of 1, Box of 25, Sterile.
510-1101-2206	05060465562623		Laserguard Silicone Ocular Shield Green OD 22mm, Units of 1, Sterile.
510-1125-2206	05060465562630		Laserguard Silicone Ocular Shield Green OD 22mm, Units of 1, Box of 25, Sterile.

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Common Specification/Harmonised Standard	Standard Title
EN ISO 13485 2016+A11:2021	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes.
EN ISO 14971 2019+A11:2021	Medical devices. Application of risk management to medical devices (ISO 14971:2019)
EN ISO 10993-10 2023	Biological evaluation of medical devices - Tests for irritation and skin sensitization
EN ISO 10993:18 2020+A1:2023	Biological evaluation of medical devices - Chemical characterization of medical device materials within a risk management process
EN ISO 11607-1 2020 +A1:2023	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems (Part 1)
EN ISO 11607-2 2020 +A1:2023	Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes (Part 2)
ISO 11737-1 2018+A1:2021	Sterilization of health care products. Microbiological methods. Determination of a population of microorganisms on products.
EN ISO 11737-2 2020	Sterilization of health care products. Microbiological methods. Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
EN ISO 11137-1 2015+A2:2019	Sterilization of health care products. Radiation. Requirements for development, validation and routine control of a sterilization process for medical devices (Part 1)
EN ISO 11137-2 2015 +A1:2023	Sterilization of health care products. Radiation. Establishing the sterilization dose (Part 2)
EN ISO 15223-1 2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements (Part 1)

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