KASHMIR SURGICAL INDIA PVT. LTD

Head Office: Plot No. 152, Phase 2, Baldev Nagar, Ambala City-134003 Haryana (**INDIA**)
Phone : +91-171-2540735, +91-981-254-1154, Email : info@kashmirsurgical.com

Declaration of Conformity

for the **"EYE OCCLUDER"**

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them, and the CE Mark may be affixed.

General Product Name:	EYE OCCLUDER
Legal Manufacturer: (Name on Label)	**KASHMIR SURGICAL INDIA PVT. LTD.** Plot No.152, Phase 2, Jaggi Garden, Baldev Nagar, Ambala City – 134007 – **INDIA**
Manufacturers SRN:	**IN-MF-000028724**
Basic UDI-DI:	As per Appendix II (This Document) - **Product Listing/Schedule**
Variants:	As per Appendix II (This Document) - **Product Listing/Schedule**
Intended Purpose:	Occluder is used to cover one eye while the other is being tested in the cover test.
MDR Classification:	Class 1/Rule 1
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	**ELLECOM GmbH.** Hauptstrasse 12, 79588 Efringen-Kirchen, Germany
EU Authorised Representative SRN:	**DE-AR-000012869**
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name Vijay Kumar **Position** Director

Signed For Kashmir Surgical India Pvt. Ltd. Director **Date** 01st Nov. 2023 **Place** AMBALA

(Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party)

KASHMIR SURGICAL INDIA PVT. LTD

Head Office: Plot No. 152, Phase 2, Baldev Nagar, Ambala City-134003 Haryana (**INDIA**)
Phone : +91-171-2540735, +91-981-254-1154, Email : info@kashmirsurgical.com

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	**Description**
MDR (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016 + A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012 / EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN 1041:2008+A1:2013	Information to be supplied by the manufacturer of medical devices

Name Vijay Kumar **Position** Director

Signed For Kashmir Surgical India Pvt. Ltd. Director **Date** 01st Nov. 2023 **Place** AMBALA

KASHMIR SURGICAL INDIA PVT. LTD

Head Office: Plot No. 152, Phase 2, Baldev Nagar, Ambala City-134003 Haryana (**INDIA**)
Phone : +91-171-2540735, +91-981-254-1154, Email : info@kashmirsurgical.com

Appendix II – Product Listing/Schedule

Catalogue No.	Device Name	EMDN Code	UDI-ID	Basic UDI-DI
DP-5004	Handheld Occluder For Eye Examination	Q0299	8906121590036	890612159DPOCCLGZ
DP-5057	Lorgnette Pinhole Occluder With Handle	Q0299	8906121590562	
DP-5064	Eye Occluder Standard	Q0299	8906121590630	

Version History: -

VERSION	COMPILED BY	DATE	DESCRIPTION
0.00	*VIJAY KUMAR*	*12/01/2022*	*1st Edition*

Name Vijay Kumar **Position** Director

Signed For Kashmir Surgical India Pvt. Ltd. Director **Date** 01st Nov. 2023 **Place** AMBALA