BASCH MEDICAL PVT. LTD.
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CIN # U46497HR2024PTC121755, PAN # AAMCB6131A, TAN # PTLB16606C, GSTIN # 06AAMCB6131A1Z5

DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 on Medical Devices (MDR Article 19)

Manufacturer:	***BASCH MEDICAL PVT. LTD.*** *Plot No.152, Jaggi Garden, Baldev Nagar, Ambala City-134003, Haryana,* ***INDIA***
Manufacturer SRN:	***IN-MF-000048187***
Product	*Eye Occluder Standard*
Model No.	*BM-12002*
GMDN	*46490*
GS1 Code	*8906200830527*
Basic UDI-DI	***890620083OCDLS***
Classification	*Class I according to Annex VIII Rule 1 of Regulation (EU) 2017/745*
Classification & Conformity Assessment	*Classification: Class I in accordance with Annex VIII, Rule 1 of Regulation (EU) 2017/745. Conformity assessment performed in accordance with Article 52(7). Technical Documentation prepared in accordance with Annex II and Annex III.*
EU Authorised Representative	***ELLECOM GmbH*** *Hauptstrasse 12, 79588 Efringen-Kirchen, Germany*
EU Authorised Representative SRN No.	***DE-AR-000012869***
Intended Purpose	*The Eye Occluder is intended to temporarily occlude one eye during ophthalmic examinations including visual acuity assessment, cover testing, refraction, orthoptic evaluation and other diagnostic eye examinations performed by healthcare professionals.*
Notified Body	*Not Applicable (Class I non-sterile, non-measuring device).*

Declaration:
We, BASCH MEDICAL PVT. LTD., hereby declare under our sole responsibility that the medical device identified in this Declaration of Conformity complies with Regulation (EU) 2017/745 on Medical Devices and all other applicable Union legislation. This Declaration of Conformity is issued under the sole responsibility of the manufacturer. Compliance with the applicable General Safety and Performance Requirements (Annex I) has been demonstrated.

Applicable Standards:
- *EN ISO 13485:2016+A11:2021*
- *EN ISO 14971:2019+A11:2021*
- *EN ISO 15223-1:2021*
- *EN ISO 20417:2021*

Conformity Assessment Procedure

This Declaration of Conformity has been drawn up in accordance with Article 19 of Regulation (EU) 2017/745. The conformity assessment procedure applicable to this Class I device has been carried out in accordance with Article 52(7).

Signed for and on behalf of **BASCH MEDICAL PVT. LTD.**

Basch Medical Pvt. Ltd.
Director

Signature:	Name:	Position:	Place & Date
	Vijay Kumar	Director	Ambala Dt. 23nd July, 2026