



BASCH MEDICAL PVT. LTD.

Plot No. 152, Jaggi Garden, Baldev Nagar,
Ambala City-134003 (HR) INDIA
Phone : +91-829-585-2255

eMail : info@baschmedical.com | www.baschmedical.com

Declaration of Conformity

for the **"WORTH 4 DOT LIGHT WITH GOGGLES"**

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:	WORTH 4 DOT LIGHT WITH GOGGLES
Legal Manufacturer: (Name on Label)	BASCH MEDICAL PVT. LTD. Plot No.152, Jaggi Garden, Baldev Nagar, Ambala City – 134003 – INDIA
Manufacturers SRN:	IN-MF-000048187
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 13
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 **Basch Medical Pvt. Ltd.**

Date 20th July, 2025

Place AMBALA

Director

(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)

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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 **Basch Medical Pvt. Ltd.**

Date 20th July, 2025

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Appendix II – Product Listing/Schedule

Catalogue No.	Device Name	EMDN Code	Basic UDI-DI
BM-13001	Worth's for Dot Test with RED GREEN glasses	Q0299	890620083W4DOTDX

Version History: -

VERSION
1.00

COMPILED BY
VIJAY KUMAR

DATE
20th July, 2025

DESCRIPTION
1st Edition

Name Vijay Kumar

Position Director

Signed **Basch Medical Pvt. Ltd.**

Date 20th July, 2025

Place AMBALA


Director