

EU Declaration of Conformity

(According to Annex IV of REGULATION (EU) 2017/745)

(1)	Manufacturer Name	Bernell Corporation
(2)	Single Registration Number	US-MF-000041111
(3)	Manufacturer Address	4016 N. Home St. Mishawaka, IN 46545 USA
(4)	Manufacturer Contact Information	Phone: +1.574.259.2070 Email: info@bernell.com
(5)	Authorized Representative Name	MedEnvoy Global B.V.
(6)	Authorized Representative Single Registration Number	NL-AR-000024028
(7)	Authorized Representative Address	Prinses Margrietplantsoen 33 - Suite 123 2595 AM The Hague The Netherlands
(8)	Authorized Representative Contact Information	Phone: +31 70 326 2148 Email: info@medenvoyglobal.com
(9)	Product Family Name	Haidinger Brush Imager
(10)	Risk Class of the Devices	Class I, Non-contact or transitory, non-sterile, non-measuring, non-invasive, non-active Annex VIII
(11)	Certificate(s) of conformity	Not applicable
(12)	Conformity assessment procedure	Annex II
(13)	We hereby declare that the medical device(s) specified in the attachment are/is in compliance with	<ul style="list-style-type: none"> - Regulation (EU) 2017/745: Demonstrating compliance with the General Safety and Performance Requirements of Annex I - 94/62/EEC: relating to packaging and packing waste - 1907/2006: registration, evaluation, authorization, and restriction of chemicals (REACH)
(14)	Applicable Common Specifications	Not applicable
(15)	Intended Purpose	Evaluate the visual function of the macula by generating a visual image known as a Haidinger Brush
(16)	Technical Documentation of reference	See in attached document
(17)	Expiry date of this Declaration	For 5 years from the signature of the declaration

(18) This Declaration of Conformity is issued under the sole responsibility of Bernell Corporation, a division of Vision Training Products, Inc.

Date: April 1, 2024



Chris Andrews

President, Bernell Corporation

Place of Issue: 4016 N. Home St., Mishawaka, Indiana 46545 USA

Attachment to EU Declaration of Conformity for Haidinger Brush Imager
++B945HBIS2
 Medical Device List

GMDN Codes:	32688
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Diagnostic Ophthalmic Prisms	
(19) BASIC UDI-DI	++B945HBIS2
(20) Description of the Device	Haidinger Brush Imager
(21) GMDN Code	32688
(22) Rule applied for the classification (Annex VIII)	I
(23) Reference of the Technical Document	TF-HBI-001
(24) Applicable Common Specifications	Not applicable

(25) Reference Number	(26) Description
BC1035	Blue/Black Goggle with Elastic
BC1041	MIT Cross - Blue Filter Slide
BC1042	MIT - Blue Filter Slide
BC1044	MIT Training Mazes (Set of 8)
BC675C	Macular Integrity Tester Version 1.0 - Complete Kit
BC675INC	Macular Integrity Tester (MIT) - Instrument Only
MIT2	Macula Integrity Tester Version II - Complete Kit
MIT2U	Macula Integrity Tester Version II - Unit only with Blue Filter Slide