

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	Ocular Occluder/Maddox Devices
(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	Hand-operated, reusable non-powered ophthalmic devices designed for use in eyesight examinations by temporarily blocking or reducing light reaching the eye.
(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: May 22, 2025



Chris Andrews

President, Bernell Corporation

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

Attachment to EU Declaration of Conformity for Ocular Occluder/Maddox Devices ++B945OOMDFS

Medical Device List

GMDN Codes:	37337
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Diagnostic Ophthalmic Prisms	
(19) BASIC UDI-DI	++B945OOMDFS
(20) Description of the Device	Ocular Occluder/Maddox Devices
(21) GMDN Code	37337
(22) Rule applied for the classification (Annex VIII)	I
(23) Reference of the Technical Document	TF-OOMD-001
(24) Applicable Common Specifications	Not applicable

(25) Reference Number	(26) Description
AMASK	Mask Occluder
ASPSR	Red Maddox Filter on Stick
BC1103	Bagolini Striated Lenses in Reversible Frames
BC1190C	Bernell Deluxe Reversible Occluder Frame
BC1200C	Clear Maddox Short Handle
BC1200G	Green Maddox Occluder - Single End
BC1200R	Red Maddox Occluder - Single End
BC1201B	Vinyl Occluder - Black
BC1201W	Vinyl Occluder - White
BC1203	Black Cupped Multiple Pinhole Occluder
BC1203P	Multi-Pinhole Occluder
BC1209F	Phoria Card - Distance Test Card
BC1209FL	Phoria Card for Distance - Led Lighted Version
BC1209N	Phoria Card - Near Test Card
BC1209NL	Phoria Card for Near - Led Lighted Version
BC1210	Single Pinhole Occluder
BC1210P	Single Pinhole Occluder
BC1211	Phoria Measure
BC1284OC	Flipper Occluder
BC204	Black Occluder - Single End
BC204P	Solid Occluder - Black
BC205	Red Maddox Acrylic Occluder - Single End
BC205P	Red Maddox Single End Occluder



A DIVISION OF VISION TRAINING PRODUCTS, INC.

BC207	Red Maddox and Black Occluder - Double End
BC207CF	White Maddox and Clear Occluder - Double End
BC207CP	Clear Plastic Maddox Occluder - Long Handle
BC207P	Double End Occluder: Red Maddox and Black
BC207PT	Double End Occluder: Red Maddox and Translucent
BC208	Plain Black and Plain Red Occluder - Double End
BC209	Red Maddox and Plain Red Occluder - Double End
BC210P	Single End White Cupped Occluder (ABS Plastic)
BC210T	Frosted Translucent Occluder - Single End (Approx. 20/400)
BC214SET	Translucent Occluder Set of 3 (Approx. 20/100 20/200 & 20/400)
BC3009	Clip-On Occluder - Black
BC3009T	Clip-On Occluder - Translucent
BC3010	Multi-Pinhole Occluder with Spring Clips
BC3013B	Lightweight Clip-On Occluder (Black)
BC3013LT	Lightweight Clip-On Occluder (Translucent)
BC3013R	Lightweight Clip-On Occluder - Red Filter
BC7019	Occlud-A-Measure
BCSBS	School Bus Test
BNWB	Bernell Streff Bi-Nasal Wedge - Black
BNWKIT	Bernell Streff Bi-Nasal Wedge - (1) Black & (1) Translucent
BNWT	Bernell Streff Bi-Nasal Wedge - Translucent
CP20100	Cling Patch 20/100 (Pkg. of 10)
CP20200	Cling Patch 20/200 (Pkg. of 10)
CP20400	Cling Patch 20/400 (Pkg. of 10)
CPSET	Cling Patch - 3 of Each (20/100_ 20/200_ 20/400)
FRBNR	Filar Bi-Nasal Ruler
HP12	Disposable Occluders Pkg. of 12
LSL100	Handheld Bagolini Striated Lens Set with Penlight
MRTSET	Maddox Rod Testing Set with Case (Red & White)
TLRBS	Bagolini Striated Trial Lens - Set of 2
TLRMC	Trial Lens - Clear Maddox
TLRMG	Trial Lens - Green Maddox
TLRMR	Trial Lens - Red Maddox
U104A46B	Clip-On Occluder - 46mm (Black) - Dozen
U104A46F	Clip-On Occluder - 46mm (Flesh) - Dozen
U104A48B	Clip-On Occluder - 48mm (Black) - Dozen
U104A48F	Clip-On Occluder - 48mm (Flesh) - Dozen
U104A50B	Clip-On Occluder - 50mm (Black) - Dozen
U104A50F	Clip-On Occluder - 50mm (Flesh) - Dozen