

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	Vision Testing Flipper
(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	Usable by healthcare professionals for vision diagnostic purposes for such visual skills as accommodative function. It is designed as a reusable tool in ophthalmic care.
(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 Vision Testing Flipper ++B945VTFVQ Medical Device List

GMDN Codes:	64350
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Diagnostic Ophthalmic Prisms	
(19) BASIC UDI-DI	++B945VTFVQ
(20) Description of the Device	Vision Testing Flipper
(21) GMDN Code	64350
(22) Rule applied for the classification (Annex VIII)	I
(23) Reference of the Technical Document	TF-VTF-001
(24) Applicable Common Specifications	Not applicable

(25) Reference Number	(26) Description
BC1270+2-4	Accommodative Flipper (+2.00D/-4.00D)
BC1270+2-4NI	Accommodative Flipper - No Imprint (+2.00D/-4.00D)
BC1270100	Accommodative Flipper (+1.00D/-1.00D)
BC1270100NI	Accommodative Flipper - No Imprint (+1.00D/-1.00D)
BC1270125	Accommodative Flipper (+1.25D/-1.25D)
BC1270125NI	Accommodative Flipper - No Imprint (+1.25D/-1.25D)
BC1270150	Accommodative Flipper (+1.50D/-1.50D)
BC1270150NI	Accommodative Flipper - No Imprint (+1.50D/-1.50D)
BC1270175	Accommodative Flipper (+1.75D/-1.75D)
BC1270175NI	Accommodative Flipper - No Imprint (+1.75D/-1.75D)
BC1270200	Accommodative Flipper (+2.00D/-2.00D)
BC1270200NI	Accommodative Flipper - No Imprint (+2.00D/-2.00D)
BC1270225	Accommodative Flipper (+2.25D/-2.25D)
BC1270225NI	Accommodative Flipper - No Imprint (+2.25D/-2.25D)
BC127025	Accommodative Flipper (+0.25D/-0.25D)
BC1270250	Accommodative Flipper (+2.50D/-2.50D)
BC1270250NI	Accommodative Flipper - No Imprint (+2.50D/-2.50D)
BC12702550	Accommodative Flipper (+/-0.25D & +/-0.50D)
BC12702550NI	Accommodative Flipper (+/-0.25D & +/-0.50D) - No Imprint
BC127025NI	Accommodative Flipper - No Imprint (+0.25D/-0.25D)
BC1270275	Accommodative Flipper (+2.75D/-2.75D)
BC1270275NI	Accommodative Flipper - No Imprint (+2.75D/-2.75D)
BC1270300	Accommodative Flipper (+3.00D/-3.00D)
BC1270300NI	Accommodative Flipper - No Imprint (+3.00D/-3.00D)



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BC1270325	Accommodative Flipper (+3.25D/-3.25D)
BC1270325NI	Accommodative Flipper - No Imprint (+3.25D/-3.25D)
BC1270350	Accommodative Flipper (+3.50D/-3.50D)
BC1270350NI	Accommodative Flipper - No Imprint (+3.50D/-3.50D)
BC1270375	Accommodative Flipper (+3.75D/-3.75D)
BC1270375NI	Accommodative Flipper - No Imprint (+3.75D/-3.75D)
BC1270400	Accommodative Flipper (+4.00D/-4.00D)
BC1270400NI	Accommodative Flipper - No Imprint (+4.00D/-4.00D)
BC127050	Accommodative Flipper (+0.50D/-0.50D)
BC1270500	Accommodative Flipper (+5.00D/-5.00D)
BC1270500NI	Accommodative Flipper - No Imprint (+5.00D/-5.00D)
BC127050NI	Accommodative Flipper - No Imprint (+0.50D/-0.50D)
BC127075	Accommodative Flipper (+0.75D/-0.75D)
BC127075NI	Accommodative Flipper - No Imprint (+0.75D/-0.75D)
BC1270PLANO	Bernell Plano Flipper
BC1270S	Special Order Flipper
BC1270SET	Flipper Set w/ Case - 6 Piece (+/-0.25D 0.50D 1.00D 1.50D 2.00D 2.50D)
BC1270SETH	Flipper Set w/ Acrylic Holder - 6 Piece (+/-0.25D 0.50D 1.00D 1.50D 2.00D 2.50D)
BC1270SETSP	Flipper Set - 6 Piece (Customer Choice)
BC1275.25	Prism Flipper - 0.25PD Prisms (0.50PD Range)
BC1275.25CC	Corrected Curve Prism Flipper - 0.25PD Prisms (0.50PD Range)
BC1275.5	Prism Flipper - 0.50PD Prisms (1PD Range)
BC1275.50CC	Corrected Curve Prism Flipper - 0.50PD Prisms (1PD Range)
BC1275.75	Prism Flipper - 0.75PD Prisms (1.50PD Range)
BC1275.75CC	Corrected Curve Prism Flipper - 0.75PD Prisms (1.50PD Range)
BC12751	Prism Flipper - 1PD Prisms (2PD Range)
BC12751.5	Prism Flipper - 1.5PD Prisms (3PD Range)
BC12751CC	Corrected Curve Prism Flipper - 1PD Prisms (2PD Range)
BC12752	Prism Flipper - 2PD Prisms (4PD Range)
BC12752CC	Corrected Curve Prism Flipper - 2PD Prisms (4PD Range)
BC12753	Prism Flipper - 3PD Prisms (6PD Range)
BC12753CC	Corrected Curve Prism Flipper - 3PD Prisms (6PD Range)
BC12754	Prism Flipper - 4PD Prisms (8PD Range)
BC12754CC	Corrected Curve Prism Flipper - 4PD Prisms (8PD Range)
BC12755	Prism Flipper - 5PD Prisms (10PD Range)
BC12755CC	Corrected Curve Prism Flipper - 5PD Prisms (10PD Range)
BC12756	Prism Flipper - 6PD Prisms (12PD Range)
BC12756CC	Corrected Curve Prism Flipper - 6PD Prisms (12PD Range)
BC12757	Prism Flipper - 7PD Prisms (14PD Range)
BC12757CC	Corrected Curve Prism Flipper - 7PD Prisms (14PD Range)
BC1275ESET	Economy Prism Flipper Set of 4 - Specify Powers (0.25 , 0.50 , 1-7PD)



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BC1275S	Special Order Prism Flipper
BC1275SCC	Special Order Corrected Curve Prism Flipper
BC1275SET	Prism Flipper Set - 6 Piece (2D/3D/4D/5D/6D/8D)
BC1275SETCC	Corrected Curve Prism Flipper Set - 6 Piece (2D/3D/4D/5D/6D/8D)
BC1275VF	Vergence Facility Prism Flipper 12D BO Range 3D BI Range (6PD and 1.5PD Prisms)
BC127610	Prism Flipper - 10PD Prisms (20PD Range)
BC127610CC	Corrected Curve Prism Flipper - 10PD Prisms (20PD Range)
BC127612	Prism Flipper - 12PD Prisms (24PD Range)
BC127615	Prism Flipper - 15PD Prisms (30PD Range)
BC127620	Prism Flipper - 20PD Prisms (40PD Range)
BC12768	Prism Flipper - 8PD Prisms (16PD Range)
BC12768CC	Corrected Curve Prism Flipper - 8PD Prisms (16PD Range)
BC12769	Prism Flipper - 9PD Prisms (18PD Range)
BC12769CC	Corrected Curve Prism Flipper - 9PD Prisms (18PD Range)
BC1276S	Special Order Prism Flipper - 8-10PD
BC1276SCC	Special Order Corrected Curve Prism Flipper - (8-10PD)
BC1277100	Rock Flipper (+1.00/-1.00)
BC1277125	Rock Flipper (+1.25/-1.25)
BC1277150	Rock Flipper (+1.50/-1.50)
BC1277175	Rock Flipper (+1.75/-1.75)
BC1277200	Rock Flipper (+2.00/-2.00)
BC1277225	Rock Flipper (+2.25/-2.25)
BC127725	Rock Flipper (+0.25/-0.25)
BC1277250	Rock Flipper (+2.50/-2.50)
BC1277275	Rock Flipper (+2.75/-2.75)
BC1277300	Rock Flipper (+3.00/-3.00)
BC1277325	Rock Flipper (+3.25/-3.25)
BC1277350	Rock Flipper (+3.50/-3.50)
BC1277375	Rock Flipper (+3.75/-3.75)
BC1277400	Rock Flipper (+4.00/-4.00)
BC127750	Rock Flipper (+0.50/-0.50)
BC127775	Rock Flipper (+0.75/-0.75)
BC12780.25	BD/BU Prism Flipper - 0.25PD Prisms
BC12780.50	BD/BU Prism Flipper - 0.50PD Prisms
BC12780.75	BD/BU Prism Flipper - 0.75PD Prisms
BC12781	BD/BU Prism Flipper - 1PD Prisms
BC12781.50	BD/BU Prism Flipper - 1.50PD Prisms
BC12782	BD/BU Prism Flipper - 2PD Prisms
BC12782.50	BD/BU Prism Flipper - 2.50PD Prisms
BC12783	BD/BU Prism Flipper - 3PD Prisms
BC12784	BD/BU Prism Flipper - 4PD Prisms



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BC1278ESET	BD/BU Prism Flipper Set of 4 - Specify Powers
BC1284100	Hyperopia Screening Flipper (+1.00)
BC1284125	Hyperopia Screening Flipper (+1.25)
BC1284150	Hyperopia Screening Flipper (+1.50)
BC1284175	Hyperopia Screening Flipper (+1.75)
BC1284200	Hyperopia Screening Flipper (+2.00)
BC1284225	Hyperopia Screening Flipper (+2.25)
BC1284250	Hyperopia Screening Flipper (+2.50)
BC1284300	Hyperopia Screening Flipper (+3.00)
BC4F	White Flipper with 4 Empty Cells
BC4FB	Empty Black Flipper with 4 Cells
BTFLIP	Bernell Tannen Flipper
MDKIT	Monovision Demo Kit
MFLIP-.25	Monocular Flipper -0.25D
MFLIP-.50	Monocular Flipper -0.50D
MFLIP-.75	Monocular Flipper -0.75D
MFLIP+.25	Monocular Flipper +0.25D
MFLIP+.50	Monocular Flipper +0.50D
MFLIP+.75	Monocular Flipper +0.75D
MFLIP+1.00	Monocular Flipper +1.00D
MFLIP+1.25	Monocular Flipper +1.25D
MFLIP+1.50	Monocular Flipper +1.50D
MFLIP+1.75	Monocular Flipper +1.75D
MFLIP+10.00	Monocular Flipper +10.00D
MFLIP+2.00	Monocular Flipper +2.00D
MFLIP+2.25	Monocular Flipper +2.25D
MFLIP+2.50	Monocular Flipper +2.50D
MFLIP+2.75	Monocular Flipper +2.75D
MFLIP+3.00	Monocular Flipper +3.00D
MFLIP+3.25	Monocular Flipper +3.25D
MFLIP+3.50	Monocular Flipper +3.50D
MFLIP+3.75	Monocular Flipper +3.75D
MFLIP+4.00	Monocular Flipper +4.00D
MFLIP+4.50	Monocular Flipper +4.50D
MFLIP+5.00	Monocular Flipper +5.00D
MFLIP+5.50	Monocular Flipper +5.50D
MFLIP+6.00	Monocular Flipper +6.00D
MFLIP+7.00	Monocular Flipper +7.00D
MFLIP+8.00	Monocular Flipper +8.00D
MFLIP-1.00	Monocular Flipper -1.00D
MFLIP-1.25	Monocular Flipper -1.25D



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MFLIP-1.50	Monocular Flipper -1.50D
MFLIP-1.75	Monocular Flipper -1.75D
MFLIP-10.00	Monocular Flipper -10.00D
MFLIP-2.00	Monocular Flipper -2.00D
MFLIP-2.25	Monocular Flipper -2.25D
MFLIP-2.50	Monocular Flipper -2.50D
MFLIP-2.75	Monocular Flipper -2.75D
MFLIP-3.00	Monocular Flipper -3.00D
MFLIP-3.25	Monocular Flipper -3.25D
MFLIP-3.50	Monocular Flipper -3.50D
MFLIP-3.75	Monocular Flipper -3.75D
MFLIP-4.00	Monocular Flipper -4.00D
MFLIP-4.50	Monocular Flipper -4.50D
MFLIP-5.00	Monocular Flipper -5.00D
MFLIP-5.50	Monocular Flipper -5.50D
MFLIP-6.00	Monocular Flipper -6.00D
MFLIP-7.00	Monocular Flipper -7.00D
MFLIP-8.00	Monocular Flipper -8.00
MFLIPE	Empty Monocular Flipper (for 48mm lenses)