

## EU Declaration of Conformity

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

(1)	<b>Manufacturer Name</b>	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 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"> <li>- <b>Regulation (EU) 2017/745:</b> Demonstrating compliance with the General Safety and Performance Requirements of Annex I</li> <li>- <b>94/62/EEC:</b> relating to packaging and packing waste</li> <li>- <b>1907/2006:</b> registration, evaluation, authorization, and restriction of chemicals (REACH)</li> </ul>
(14)	Applicable Common Specifications	Not applicable
(15)	Intended Purpose	Usable by healthcare professionals for various vision assessments and determination of visual capabilities. Designed as reusable tools for use in ophthalmic care or other general healthcare settings.
(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 Device

### ++B945VTDVL

### Medical Device List

<b>GMDN Codes:</b>	<b>16800</b>
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Diagnostic Ophthalmic Prisms	
<b>(19) BASIC UDI-DI</b>	++B945VTDVL
<b>(20) Description of the Device</b>	Vision Testing Devices
<b>(21) GMDN Code</b>	16800
<b>(22) Rule applied for the classification (Annex VIII)</b>	I
<b>(23) Reference of the Technical Document</b>	TF-VTD-001
<b>(24) Applicable Common Specifications</b>	Not applicable

(25) Reference Number	(26) Description
ARMDMAG	Magnetic ARMD Card 6.5" x 5" All Black
ARMDMAGIMP	Imprinted Magnetic ARMD Pads (Minimum 500)
ASTBI	Translid Binocular Interactor (TBI) with Variable PD and Speed Knobs
BC1025	Bernell Stereo Test Book with Red/Green Goggles
BC1185PH	Bernell Pinhole Glasses (Modern Model Frame)
BC1189PH	Bernell Pinhole Glasses (New Age Frame)
BC11910	10ft Snellen "E" Test Chart
BC11931	20ft Snellen "E" Test Chart
BC11942	Tumbling E 20ft Distance Chart
BC1196670	Vocational Near Test Card
BC1196871	A.M.A. English Reading Card
BC11980	SMD (Amsler Grid) Test Card
BC11981	Near Point Test Card (MEM)
BC1243	Large Kindergarten Vision Test Chart
BC1261	Snellen 20ft Test Chart
BC1262	Illiterate 20ft Test Chart
BC1263	Kindergarten 20ft Test
BC1264	10ft Test Chart
BC21	Replacement Cards for GR50
BC210	White Occluder - Single End
BC2171	Placido Disc/Clip/Handle
BC2202	Near Acuity Test Card (4.5pt To 24 pt)
BC2203	Near Acuity Test Card - Newspaper (8pt To 48 pt)



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BC2204	Near Acuity Test Card - Plane/Phone/Shorthand
BC2205	Near Acuity Test Card - French and Spanish (4.5pt To 12pt)
BC2206	Near Acuity Test Card - Tumbling E (5.5pt To 8pt)
BC2207	Near Acuity Test Card - Child Recognition & Playing Cards
BC2208	Near Acuity Test Card - Illus of The Ocular Adnexa
BC2210	Near Vocational Test Set - Book with 7 Cards
BC2245	Amsler Grid Book
BC35	3-Dot Graded Anti-Suppression Tranaglyph with Red/Green Flipper
BC4001	Tangent Screen
BC4001W	Tangent Screen - Replacement Wand & Targets
BC4022	Hand Disc Perimeter
BC4022W	Hand Disc Perimeter - Replacement Wand & Targets
BC553A	Near Point Analysis Slide - for Test Lantern
BC553BRF	Binocular Refraction at Far Slide for Test Lantern
BC553BRN	Binocular Refraction at Near Slide for Test Lantern
BC553FDF	Fixation Disparity at Far Slide (Non-Rotary) for Test Lantern
BC553P	Phoria Slide for Test Lantern
BC553TL	Test Lantern with Built-In Worth 4-Dot
BC7	White Plastic Ruler
BC71MR	Multi Rule - Inch & mm Scale
BC814SCJ	Snellen X-Cyl Jaeger Card
BC815	Jaeger Test Card
BC816AMA	A.M.A. Near Point Test Card
BC817	Berens Accommodation Reading Card
BC9PGC1	Bernell 9 Positions of Gaze Chart
BCAOA	AOA Near Acuity Card
BCBS538	Worth 4-Dot LED Flashlight with R/G Goggles
BCBS548	Worth Test with Letters with Red/Green Glasses
BCCUBE1	Bernell Fixation Cube with Acuity Check
BCDI	HOTV 20ft Distance Test
BCDI10	HOTV 10ft Test
BCE10	Tumbling "E" Test
BCFBAT1	Bernell Functional Binocular Assessment Test (FBAT)
BCFDC	Fixation Disparity Card with Polarized Goggles
BCFIX	Bernell Fixation Stick
BCLD10	Sloan Letter 10ft Test
BCNI	HOTV Near Vision Acuity Card
BCNIE	HOTV Near Vision Acuity Card with Elastic
BCPDC	Clear Plastic Ruler
BCRETCARDS	Bernell Retinoscopy Card Set
BCS10	Symbol 10ft Test Chart



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BCSALCD	Saladin Card
BCSALCDK1	The Saladin Near Point Balance Card- Kit with Light Box
BCSMDGRID	Amsler Grid/Refined Central (Pad of 50)
BCSMDP	Amsler Grid Test - Pad of 50
BCTORTEST	Bernell Torsion Test
BCVDISC	Bernell Vision Disc
BCVTA	Vision Test Card Book
BCVTPK2G	Pre-Kindergarten Test Book
BERAI	Bernell After Image Generator
BESTD1	Bernell Evaluation of Stereopsis Test - Dinosaur Edition
BS528FL	Three Figure LED Flashlight with Reversible Goggles
BSCREEN	Public Vision Screening Card Comes with Red/Green Flipper
BSRETH1	Bernell Spot Retinoscope Head
BWT	Broken Wheel Test
BWTRC	Broken Wheel Test for Near
DAL300	Optokinetic Drum - Adult
DAL301	Pediatric Optokinetic Drum 10.5" H x 8" Diameter
DBLC036	Astigmatism -Translucent Backlit Eyechart 17" x 10" Size
GR50	Accommodative Convergence Rule
GR50CH	Card Holder
HDTEST	Howard-Dolman Test
JRFDP	Richman Face Dot Test Paddle
LVCARD	Low Vision Test Card
LVDAC	Low Vision Distance Acuity Chart 11" x 14" Size
MDEP	Bernell MDEP Pupillometer - Pkg. of 5
MTBIFL	TBI with Flex Extenders
MTBIH2	Handheld TBI: Version 2.0 (PD 65mm)
ODNVC	Near Vision Card
OKNADP1	Pediatric OKN Banner Adapter
OKNKIT	OKN Banner
PCARD	Phoropter Near Point Card
PCARDPA	Polarized Phoropter Test
PCARDSET	Phoropter Card Set
PCCLIP	Phoropter Card Holder
PENPKIT2	MDEP LED Penlight & Pupillometer Combo Set
PHROD	Phoropter Replacement Rod
PVT	Preschool Vision Test
RPS	Rosenbaum Pocket Vision Screener
SSCARD	School Screening Card Set
WFC	Wesson Fixation Disparity Card Includes Goggle