

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	Ophthalmic Trial Lenses
(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	Lenses of various dioptric powers, used primarily for vision testing to ascertain the necessary refraction for a patient.
(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: October 17, 2024



Chris Andrews
President, Bernell Corporation
Place of Issue: 4016 N. Home St., Mishawaka, Indiana 46545 USA

Attachment to EU Declaration of Conformity for Ophthalmic Trial Lens Frame ++B945OTLSHE Medical Device List

GMDN Codes:	36068
--------------------	--------------

Diagnostic Ophthalmic Prisms	
(19) BASIC UDI-DI	++B945OTLSHE
(20) Description of the Device	Ophthalmic Trial Lenses
(21) GMDN Code	36068
(22) Rule applied for the classification (Annex VIII)	I
(23) Reference of the Technical Document	TF-OTLS-001
(24) Applicable Common Specifications	Not applicable

(25) Reference Number	(26) Description
CBAR4	Confirmation Bar with +0.50 +0.25 -0.25 -0.50
CNS232A	232 Piece Trial Lens Set with Aluminum Case
CNS266	266 Piece Trial Lens Set with Carrying Case
CNS266KIT	266 Piece Trial Lens Set with Trial Frame
CNS68L	68 Piece Trial Lens Set with Leather Case
DSLRS8	Deluxe Skiascopic Lens Rack Set
L122084	Retinoscopy Racks
HTLRPS	Trial Lens Refraction Paddle Set
LENS65-300	-3.00 Diopter 65mm Plastic Lens
TLRBCG	Trial Lens Ring with Bernell Green Vinyl Filter
TLRBCR	Trial Lens Ring with Bernell Red Vinyl Filter
TLRC-.25	Trial Lens Replacement Cylindrical -0.25
TLRC-.37	Trial Lens Replacement Cylindrical -0.37
TLRC-.50	Trial Lens Replacement Cylindrical -0.50
TLRC-.75	Trial Lens Replacement Cylindrical -0.75
TLRC+.25	Trial Lens Replacement Cylindrical +0.25
TLRC+.50	Trial Lens Replacement Cylindrical +0.50
TLRC+.75	Trial Lens Replacement Cylindrical +0.75
TLRC+1.00	Trial Lens Replacement Cylindrical +1.00
TLRC+1.25	Trial Lens Replacement Cylindrical +1.25
TLRC+1.50	Trial Lens Replacement Cylindrical +1.50
TLRC+1.75	Trial Lens Replacement Cylindrical +1.75
TLRC+2.00	Trial Lens Replacement Cylindrical +2.00
TLRC+2.25	Trial Lens Replacement Cylindrical +2.25



A DIVISION OF VISION TRAINING PRODUCTS, INC.

TLRC+2.50	Trial Lens Replacement Cylindrical +2.50
TLRC+2.75	Trial Lens Replacement Cylindrical +2.75
TLRC+3.00	Trial Lens Replacement Cylindrical +3.00
TLRC+3.25	Trial Lens Replacement Cylindrical +3.25
TLRC+3.50	Trial Lens Replacement Cylindrical +3.50
TLRC+3.75	Trial Lens Replacement Cylindrical +3.75
TLRC+4.00	Trial Lens Replacement Cylindrical +4.00
TLRC+4.25	Trial Lens Replacement Cylindrical +4.25
TLRC+4.50	Trial Lens Replacement Cylindrical +4.50
TLRC+5.00	Trial Lens Replacement Cylindrical +5.00
TLRC+5.25	Trial Lens Replacement Cylindrical +5.25
TLRC+5.50	Trial Lens Replacement Cylindrical +5.50
TLRC+5.75	Trial Lens Replacement Cylindrical +5.75
TLRC+6.00	Trial Lens Replacement Cylindrical +6.00
TLRC+7.00	Trial Lens Replacement Cylindrical +7.00
TLRC+8.00	Trial Lens Replacement Cylindrical +8.00
TLRC-0.12	Trial Lens Replacement Cylindrical -0.12
TLRC-1.00	Trial Lens Replacement Cylindrical -1.00
TLRC-1.25	Trial Lens Replacement Cylindrical -1.25
TLRC-1.50	Trial Lens Replacement Cylindrical -1.50
TLRC-1.75	Trial Lens Replacement Cylindrical -1.75
TLRC-2.00	Trial Lens Replacement Cylindrical -2.00
TLRC-2.25	Trial Lens Replacement Cylindrical -2.25
TLRC-2.50	Trial Lens Replacement Cylindrical -2.50
TLRC-2.75	Trial Lens Replacement Cylindrical -2.75
TLRC-3.00	Trial Lens Replacement Cylindrical -3.00
TLRC-3.25	Trial Lens Replacement Cylindrical -3.25
TLRC-3.50	Trial Lens Replacement Cylindrical -3.50
TLRC-3.75	Trial Lens Replacement Cylindrical -3.75
TLRC-4.00	Trial Lens Replacement Cylindrical -4.00
TLRC-4.25	Trial Lens Replacement Cylindrical -4.25
TLRC-4.50	Trial Lens Replacement Cylindrical -4.50
TLRC-4.75	Trial Lens Replacement Cylindrical -4.75
TLRC-5.00	Trial Lens Replacement Cylindrical -5.00
TLRC-5.25	Trial Lens Replacement Cylindrical -5.25
TLRC-5.50	Trial Lens Replacement Cylindrical -5.50
TLRC-5.75	Trial Lens Replacement Cylindrical -5.75
TLRC-6.00	Trial Lens Replacement Cylindrical -6.00
TLRC-7.00	Trial Lens Replacement Cylindrical -7.00
TLRC-8.00	Trial Lens Replacement Cylindrical -8.00
TLROF	Trial Lens Occluder (Frosted)



A DIVISION OF VISION TRAINING PRODUCTS, INC.

TLROFC	Trial Lens Occluder (Clear with Cross)
TLROO	Trial Lens Occluder (Opaque Black)
TLROPIN	Trial Lens Occluder (Black Pinhole)
TLROPIN1.5	Trial Lens Occluder (1.5mm Pinhole)
TLROSL	Trial Lens Occluder (Slit Occluder)
TLRP+0.12	Trial Lens Replacement Prism 0.12PD
TLRP+0.25	Trial Lens Replacement Prism 0.25
TLRP+0.5	Trial Lens Replacement Prism 0.5PD
TLRP+1.00	Trial Lens Replacement Prism 1PD
TLRP+1.5	Trial Lens Replacement Prism 1.5PD
TLRP+10.00	Trial Lens Replacement Prism 10PD
TLRP+12.00	Trial Lens Replacement Prism 12PD
TLRP+14.00	Trial Lens Replacement Prism 14PD
TLRP+16.00	Trial Lens Replacement Prism 16PD
TLRP+2.00	Trial Lens Replacement Prism 2PD
TLRP+2.5	Trial Lens Replacement Prism 2.5PD
TLRP+3.00	Trial Lens Replacement Prism 3PD
TLRP+4.00	Trial Lens Replacement Prism 4PD
TLRP+5.00	Trial Lens Replacement Prism 5PD
TLRP+6.00	Trial Lens Replacement Prism 6PD
TLRP+7.00	Trial Lens Replacement Prism 7PD
TLRP+8.00	Trial Lens Replacement Prism 8PD
TLRPLANO	Plano Replacement Trial Lens
TLRS-.12	Trial Lens Replacement Spherical -0.12
TLRS-.25	Trial Lens Replacement Spherical -0.25
TLRS-.37	Trial Lens Replacement Spherical -0.37
TLRS-.50	Trial Lens Replacement Spherical -0.50
TLRS-.75	Trial Lens Replacement Spherical -0.75
TLRS+.25	Trial Lens Replacement Spherical +0.25
TLRS+.37	Trial Lens Replacement Spherical +0.37
TLRS+.50	Trial Lens Replacement Spherical +0.50
TLRS+.75	Trial Lens Replacement Spherical +0.75
TLRS+0.12	Trial Lens Replacement Spherical +0.12
TLRS+0.62	Trial Lens Replacement Spherical +0.62
TLRS+1.00	Trial Lens Replacement Spherical +1.00
TLRS+1.25	Trial Lens Replacement Spherical +1.25
TLRS+1.50	Trial Lens Replacement Spherical +1.50
TLRS+1.75	Trial Lens Replacement Spherical +1.75
TLRS+10.00	Trial Lens Replacement Spherical +10.00
TLRS+11.00	Trial Lens Replacement Spherical +11.00
TLRS+12.00	Trial Lens Replacement Spherical +12.00



A DIVISION OF VISION TRAINING PRODUCTS, INC.

TLRS+12.50	Trial Lens Replacement Spherical +12.50
TLRS+13.00	Trial Lens Replacement Spherical +13.00
TLRS+14.00	Trial Lens Replacement Spherical +14.00
TLRS+15.00	Trial Lens Replacement Spherical +15.00
TLRS+16.00	Trial Lens Replacement Spherical +16.00
TLRS+18.00	Trial Lens Replacement Spherical +18.00
TLRS+2.00	Trial Lens Replacement Spherical +2.00
TLRS+2.25	Trial Lens Replacement Spherical +2.25
TLRS+2.50	Trial Lens Replacement Spherical +2.50
TLRS+2.75	Trial Lens Replacement Spherical +2.75
TLRS+20.00	Trial Lens Replacement Spherical +20.00
TLRS+3.00	Trial Lens Replacement Spherical +3.00
TLRS+3.25	Trial Lens Replacement Spherical +3.25
TLRS+3.50	Trial Lens Replacement Spherical +3.50
TLRS+3.75	Trial Lens Replacement Spherical +3.75
TLRS+4.00	Trial Lens Replacement Spherical +4.00
TLRS+4.25	Trial Lens Replacement Spherical +4.25
TLRS+4.50	Trial Lens Replacement Spherical +4.50
TLRS+4.75	Trial Lens Replacement Spherical +4.75
TLRS+5.00	Trial Lens Replacement Spherical +5.00
TLRS+5.25	Trial Lens Replacement Spherical +5.25
TLRS+5.50	Trial Lens Replacement Spherical +5.50
TLRS+5.75	Trial Lens Replacement Spherical +5.75
TLRS+6.00	Trial Lens Replacement Spherical +6.00
TLRS+6.50	Trial Lens Replacement Spherical +6.50
TLRS+7.00	Trial Lens Replacement Spherical +7.00
TLRS+7.50	Trial Lens Replacement Spherical +7.50
TLRS+8.00	Trial Lens Replacement Spherical +8.00
TLRS+8.50	Trial Lens Replacement Spherical +8.50
TLRS+9.00	Trial Lens Replacement Spherical +9.00
TLRS+9.50	Trial Lens Replacement Spherical +9.50
TLRS-0.62	Trial Lens Replacement Spherical -0.62
TLRS-1.00	Trial Lens Replacement Spherical -1.00
TLRS-1.25	Trial Lens Replacement Spherical -1.25
TLRS-1.50	Trial Lens Replacement Spherical -1.50
TLRS-1.75	Trial Lens Replacement Spherical -1.75
TLRS-10.00	Trial Lens Replacement Spherical -10.00
TLRS-10.50	Trial Lens Replacement Spherical -10.50
TLRS-11.00	Trial Lens Replacement Spherical -11.00
TLRS-12.00	Trial Lens Replacement Spherical -12.00
TLRS-13.00	Trial Lens Replacement Spherical -13.00



A DIVISION OF VISION TRAINING PRODUCTS, INC.

TLRS-14.00	Trial Lens Replacement Spherical -14.00
TLRS-15.00	Trial Lens Replacement Spherical -15.00
TLRS-16.00	Trial Lens Replacement Spherical -16.00
TLRS-18.00	Trial Lens Replacement Spherical -18.00
TLRS-2.00	Trial Lens Replacement Spherical -2.00
TLRS-2.25	Trial Lens Replacement Spherical -2.25
TLRS-2.50	Trial Lens Replacement Spherical -2.50
TLRS-2.75	Trial Lens Replacement Spherical -2.75
TLRS-20.00	Trial Lens Replacement Spherical -20.00
TLRS-3.00	Trial Lens Replacement Spherical -3.00
TLRS-3.25	Trial Lens Replacement Spherical -3.25
TLRS-3.50	Trial Lens Replacement Spherical -3.50
TLRS-3.75	Trial Lens Replacement Spherical -3.75
TLRS-4.00	Trial Lens Replacement Spherical -4.00
TLRS-4.25	Trial Lens Replacement Spherical -4.25
TLRS-4.50	Trial Lens Replacement Spherical -4.50
TLRS-4.75	Trial Lens Replacement Spherical -4.75
TLRS-5.00	Trial Lens Replacement Spherical -5.00
TLRS-5.25	Trial Lens Replacement Spherical -5.25
TLRS-5.50	Trial Lens Replacement Spherical -5.50
TLRS-5.75	Trial Lens Replacement Spherical -5.75
TLRS-6.00	Trial Lens Replacement Spherical -6.00
TLRS-6.25	Trial Lens Replacement Spherical -6.25
TLRS-6.50	Trial Lens Replacement Spherical -6.50
TLRS-7.00	Trial Lens Replacement Spherical -7.00
TLRS-7.50	Trial Lens Replacement Spherical -7.50
TLRS-8.00	Trial Lens Replacement Spherical -8.00
TLRS-8.50	Trial Lens Replacement Spherical -8.50
TLRS-9.00	Trial Lens Replacement Spherical -9.00
TLRS-9.50	Trial Lens Replacement Spherical -9.50
TOM180	Skiascopic Lens Rack (Wooden) Bamboo Case
TOM3030100	Jackson Crossed Cylinder +/-1.00
TOM3030200	Jackson Crossed Cylinder +/-2.00
TOM303025	Jackson Crossed Cylinder +/- 0.25
TOM303037	Jackson Crossed Cylinder +/-0.37
TOM303050	Jackson Crossed Cylinder +/- 0.50
TOM303075	Jackson Crossed Cylinder +/- 0.75
TOM3030SET	Jackson Crossed Cylinder +/-0.25, 0.50, 0.75, 1.00 with Case
UTL266	266 Piece Trial Lens Set with Leather Case