Medical Devices (Pvt) Ltd.
Wazirabad Road, Ugoki, Sialkot - Pakistan.

EU DECLARATION OF CONFORMITY

Manufacturer name and address:	Medical Devices (Pvt) Ltd Wazirabad Road, Ugoki Sialkot. Pakistan. Tel. +92 52 3571214 & 15 email: info@mdevices.com
SRN (Single Registration Number):	PK-MF-000021845
Authorized Representative name and address (if applicable):	Obelis s.a. Bd. Général Wahis 53 B-1030 Brussels, Belgium Phone: 32.2.732.59.54 Fax: 32.2.732.60.03 E-mail: mail@obelis.net SRN: BE-AR-000000106

We, Medical Devices (Pvt) Ltd., hereby declare under our sole responsibility that the device(s) listed in the attached Annex comply(ies) with the provisions of the REGULATION (EU) 2017/745.

The device(s) is/are Class I following Rule 1 & 13 of Annex VIII of REGULATION (EU) 2017/745.

The Conformity Assessment Procedure has been performed following Art.19 and Art. 52 (7), and Technical Documentation was drawn up following Annex II and III of the Regulation (EU) 2017/745.

The following Standards have been used and in relation to which conformity is declared:

ISO 13485:2016, ISO 14971:2019, ISO/TR 24971:2020, ISO 15223-1:2021, ISO 10993-5: 2009, ISO 10993-10: 2010, ISO 10942:2006, ISO 15004-1:2006, IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007 + AMI:2012 (or IEC 60601-1:2012), IEC 60601-1-2:2014, IEC 60601-1-6 2010 + Amd1 2013, IEC 62366-1:2015.

The present declaration is in conformity with Regulation (EU) 2017/745.

Tauseef Ajmal (RA Manager)
SIALKOT- PAKISTAN
Date: 18 May'2023

MEDICAL DEVICES (PVT) LIMITED SIALKOT PAKISTAN

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Annex - List of Devices Covered by the Declaration of Conformity

#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Description	Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	GMDN and EMDN code
1	NOVA	808-992-25 808-992-26 808-992-27 808-992-28 808-954-25 808-003-25	Ophthalmoscope Set, NOVA, Screw Locking,	For Examination of Eye	1	1 & 13	896110278 OPHS808 TN	46786 / Z12120114
2	PRIMA	808-808-25 808-808-26 808-808-27 808-808-28 808-810-25 808-810-26 808-810-27 808-810-28 808-171-25 808-013-25	Ophthalmoscope Set, PRIMA, Bayonet Locking.	For Examination of Eye	1	1 & 13	896110278 OPHS808 TN	46786 / Z12120114
3	OMNI 3000	808-454-31 808-454-32 808-454-41 808-454-42 808-454-51 808-454-52 808-456-01 808-456-02 808-456-03 808-456-11 808-456-12 808-456-21 808-456-22 808-456-31 808-456-32 808-456-41 808-456-42 808-456-51 808-456-52	Ophthalmoscope Set, OMNI 3000, Pocket Style. Xenon Multicolor – Black, Grey, Burgundy, Blue, Green, Purple	For Examination of Eye	1	1 & 13	896110278 OPHPOC808 U8	46786 / Z12120114
4	OMNI 3000	808-490-02 808-490-03 808-490-11 808-490-21 808-490-31 808-490-41 808-490-51 808-492-02 808-492-03 808-492-11 808-492-21 808-492-31 808-492-41 808-492-51	Ophthalmoscope Set, OMNI 3000, Pocket Style. LED Multicolor – Black, Grey, Burgundy, Blue, Green, Purple	For Examination of Eye	1	1 & 13	896110278 OPHPOC808 U8	46786 / Z12120114

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5	OMNI 3000	808-430-11 808-430-21 808-430-25 808-430-31 808-430-41 808-430-51 808-432-11 808-432-21 808-432-25 808-432-31 808-432-41 808-432-51 808-400-11 808-400-21 808-400-25 808-400-31 808-400-41 808-400-51 808-402-01 808-402-25	Ophthalmoscope Head, OMNI 3000. Multicolor – Black, Grey, Burgundy, Blue, Green, Purple Ophthalmoscope Handle, OMNI 3000, Standard, Pocket Style. Ophthalmoscope Rechargeable Handle, OMNI 3000, Pocket Style.	For Examination of Eye	1	1 & 13	896110278 OPHPOC808 U8	46786 / Z12120114
6	NeuVU	805-822-01 805-822-51 805-806-01 805-806-51 805-802-01	Ophthalmoscope Set, NeuVU, Pocket Style. Ophthalmoscope Head, NeuVU, Xenon & LED Ophthalmoscope Handle, NeuVU, Pocket Style	For Examination of Eye	1	1 & 13	896110278 OPHPOC808 U8	46786 / Z12120114
7	VISIO 2000	808-605-25 808-606-35 808-607-35 808-608-35 808-645-25 808-646-35 808-647-35 808-648-35	Ophthalmoscope Set, VISIO 2000, F.O.	For Examination of Eye	1	1 & 13	896110278 OPHVIS808 Y4	46786 / Z12120114
8	VISIO 2000	808-570-25 808-571-25 808-572-35 808-573-35 808-031-25 808-039-35 808-037-35 808-037-02 808-039-02 808-040-25 808-041-35 808-042-35	Ophthalmoscope Head, VISIO 2000, F.O. Ophthalmoscope Handle, VISIO 2000, F.O	For Examination of Eye	1	1 & 13	896110278 OPHVIS808 Y4	46786 / Z12120114
9	VISIO 5	805-111-25 805-116-25 805-112-35 805-117-35 805-113-35 805-118-35	Ophthalmoscope Set, VISIO 5, GE	For Examination of Eye	1	1 & 13	896110278 OPHVIS808 Y4	46786 / Z12120114

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10	VISIO 5	805-061-25 805-063-25 805-062-35 805-064-35	Ophthalmoscope Heads, VISIO 5, GE	For Examination of Eye	1	1 & 13	896110278 OPHVIS808 Y4	46786 / Z12120114
11	VISIO 5	805-121-25 805-126-25 805-122-35 805-127-35 805-123-35 805-128-35	Ophthalmoscope Set, VISIO 5, SE	For Examination of Eye	1	1 & 13	896110278 OPHVIS808 Y4	46786 / Z12120114
12	VISIO 5	805-071-25 805-073-25 805-072-35 805-074-35	Ophthalmoscope Heads, VISIO 5, SE	For Examination of Eye	1	1 & 13	896110278 OPHVIS808 Y4	46786 / Z12120114
13	VISIO 5	805-131-25 805-136-25 805-132-35 805-137-35 805-133-35 805-138-35	Ophthalmoscope Set, VISIO 5, XE	For Examination of Eye	1	1 & 13	896110278 OPHVIS808 Y4	46786 / Z12120114
14	VISIO 5	805-081-25 805-083-25 805-082-35 805-084-35	Ophthalmoscope Heads, VISIO 5, XE	For Examination of Eye	1	1 & 13	896110278 OPHVIS808 Y4	46786 / Z12120114
15	VISIO 5	805-005-35 805-007-35 805-009-35 805-001-25 805-002-35 805-004-35	Oto/Ophthalmoscope Handles VISIO 5	For Examination of Eye	1	1 & 13	896110278 OPHVIS808 Y4	46786 / Z12120114
Spare Lamps								
1	NOVA & PRIMA	833-017-25 833-021-25 833-025-25 833-027-35	Bulbs for Ophthalmoscope	-	-	-	896110278 LAMP833 LZ	-
2	OMNI 3000 & NeuVU	833-059-25 833-069-25	Bulbs for Ophthalmoscope	-	-	-	896110278 LAMP833 LZ	-
3	VISIO 5 & 2000	833-029-25 833-031-35	Bulbs for Ophthalmoscope	-	-	-	896110278 LAMP833 LZ	-
4	OMNI	833-060-25	LED for Ophthalmoscope	-	-	-	896110278 LAMP833 LZ	-
5	NeuVU	833-084-25	LED for Ophthalmoscope	-	-	-	896110278 LAMP833 LZ	-
6	VISIO 5 & 2000	833-085-25 833-087-35 833-089-25 833-091-35	LED for Ophthalmoscope	-	-	-	896110278 LAMP833 LZ	-

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