



**Medical Devices (Pvt) Ltd.**

Wazirabad Road, Ugo'ki, Sialkot - Pakistan.

**EU DECLARATION OF CONFORMITY**

**Manufacturer name and address:**

Medical Devices (Pvt) Ltd  
Wazirabad Road, Ugo'ki 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.  
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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 5 & 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:

EN ISO 13485:2016, ISO 14971:2019, ISO/TR 24971:2020, ISO 15223-1:2021, ISO 10993-5:2009, ISO 10993-10:2010, IEC 60601-1:2005+A1:2012+A2:2020, IEC 60601-1-2:2014+AMD1:2020, 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: 17 May'2023





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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	808-990-25 808-990-26 808-990-27 808-990-28	Otoscope Set, NOVA, Standard, Side Screw Locking	For Examination of Ear & Nose	1	5 and 13	896110278 OTOS808 XP	12849 / Z12021007
2	NOVA	808-950-25 808-003-25	Otoscope Head, NOVA Otoscope Handle, NOVA	For Examination of Ear & Nose	1	5 and 13	896110278 OTOS808 XP	12849 / Z12021007
3	PRIMA	808-800-25 808-800-26 808-800-27 808-800-28 808-802-25 808-802-26 808-802-27 808-802-28 808-804-25 808-804-26 808-804-27 808-804-28 808-806-25 808-806-26 808-806-27 808-806-28 808-824-25 808-824-26 808-824-27 808-824-28	Otoscope Set, PRIMA, Standard Bayonet Locking.	For Examination of Ear & Nose	1	5 and 13	896110278 OTOS808 XP	12849 / Z12021007
4	PRIMA	808-100-25 808-112-25 808-108-25 808-013-25	Otoscope Head, PRIMA  Operating Otoscope Head, PRIMA  Otoscope Slit Illumination Head, PRIMA  Otoscope Handle, PRIMA	For Examination of Ear & Nose	1	5 and 13	896110278 OTOS808 XP	12849 / Z12021007



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5	OMNI 3000	808-450-01 808-450-02 808-450-03 808-450-11 808-450-12 808-450-21 808-450-22 808-450-31 808-450-32 808-450-41 808-450-42 808-450-51 808-450-52 808-452-01 808-452-02 808-452-03 808-452-11 808-452-12 808-452-21 808-452-22 808-452-31 808-452-32 808-452-41 808-452-42 808-452-51 808-452-52 808-480-02 808-480-03 808-480-11 808-480-21 808-480-31 808-480-41 808-480-51 808-482-02 808-482-03 808-482-11 808-482-21 808-482-31 808-482-41 808-482-51 808-466-01 808-466-02 808-464-01	Otoscope Set, OMNI 3000, F.O. Pocket Style.  Multicolor – Black, Grey, Burgundy, Blue, Green, Purple	For Examination of Ear and Nose	1	5 and 13	896110278 OTOPOC808 2E	12849 / Z12021007
6	OMNI 3100	808-470-02 808-470-11 808-470-21 808-470-31 808-470-41 808-470-51 808-472-02 808-472-11 808-472-21 808-472-31 808-472-41 808-472-51	Otoscope Set, OMNI 3100, Standard, Pocket Style	For Examination of Ear	1	5 and 13	896110278 OTOPOC808 2E	12849 / Z12021007

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7	OMNI 3000	808-410-11 808-410-21 808-410-25 808-410-31 808-410-41 808-410-51 808-412-11 808-412-21 808-412-25 808-412-31 808-412-41 808-412-51 808-416-25 808-414-25	Otoscope Head, OMNI 3000.  Multicolor – Black, Grey, Burgundy, Blue, Green, Purple.	For Examination of Ear & Nose	1	5 and 13	896110278 OTOPOC808 2E	12849 / Z12021007
8	OMNI 3100	808-420-11 808-420-21 808-420-25 808-420-31 808-420-41 808-420-51	Otoscope Head, OMNI 3100, Pocket Style	For Examination of Ear	1	5 and 13	896110278 OTOPOC808 2E	12849 / Z12021007
9	OMNI 3000/3100	808-400-11 808-400-21 808-400-25 808-400-31 808-400-41 808-400-51 808-402-01 808-402-25	Otoscope Handle OMNI 3000/3100, Pocket Style  Multicolor – Black, Grey, Burgundy, Blue, Green, Purple.	For Examination of Ear	1	5 and 13	896110278 OTOPOC808 2E	12849 / Z12021007
10	NeuVU	805-830-01 805-830-11 805-830-21 805-830-31 805-830-41 805-830-51 805-820-01 805-820-51	Otoscope Set, NeuVU, F.O., Pocket Style.  Multicolor – Black, Grey, Burgundy, Blue, Green, Purple	For Examination of Ear	1	5 and 13	896110278 OTOPOC808 2E	12849 / Z12021007
11	NeuVU	805-814-01 805-814-11 805-814-21 805-814-31 805-814-41 805-814-51 805-802-01 805-802-11 805-802-21 805-802-31 805-802-41 805-802-51 805-804-01 805-804-51	Otoscope Head, NeuVU, F.O. Pocket Style.  Otoscope Handle, NeuVU, Pocket Style  Multicolor – Black, Grey, Burgundy, Blue, Green, Purple	For Examination of Ear	1	5 and 13	896110278 OTOPOC808 2E	12849 / Z12021007
12	VISIO V-Max	805-301-35 805-311-35 805-302-35 805-312-35 805-303-35 805-313-35	Otoscope Set, VISIO V- Max, F.O.	For Examination of Ear	1	5 and 13	896110278 OTOVIS808 6A	12849 / Z12021007

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13	VISIO V-Max	805-041-35 805-042-35	Otoscope Head, VISIO V-Max, F.O.	For Examination of Ear	1	5 and 13	896110278 OTOVIS808 6A	12849 / Z12021007
14	VISIO 5	805-101-25 805-106-25 805-102-35 805-107-35 805-103-35 805-108-35	Otoscope Set, VISIO 5, F.O.	For Examination of Ear	1	5 and 13	896110278 OTOVIS808 6A	12849 / Z12021007
15	VISIO 5	805-021-25 805-022-35 805-031-35 805-032-35	Otoscope Head, VISIO 5, F.O.	For Examination of Ear	1	5 and 13	896110278 OTOVIS808 6A	12849 / Z12021007
16	VISIO 1500	808-630-25 808-631-35 808-632-35 808-633-35 808-670-25 808-671-35 808-672-35 808-673-35	Otoscope Set, VISIO 1500, Standard.	For Examination of Ear & Nose	1	5 and 13	896110278 OTOVIS808 6A	12849 / Z12021007
17	VISIO 1500	808-538-25 808-540-35 808-546-25 808-548-35	Operating Otoscope Head, VISIO 1500  Otoscope Head, VISIO 1500.	For Examination of Ear	1	5 and 13	896110278 OTOVIS808 6A	12849 / Z12021007
18	VISIO 2000	808-600-25 808-601-35 808-602-35 808-603-35 808-640-25 808-641-35 808-642-35 808-643-35	Otoscope Set, VISIO 2000, F.O.	For Examination of Ear & Nose	1	5 and 13	896110278 OTOVIS808 6A	12849 / Z12021007
19	VISIO 2000	808-531-25 808-533-35 808-534-25 808-536-35 808-500-25 808-502-35	Otoscope Head, VISIO 2000, F.O.	For Examination of Ear & Nose	1	5 and 13	896110278 OTOVIS808 6A	12849 / Z12021007

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20	VISIO 2000	805-001-25 805-002-35 805-004-35 805-005-35 805-007-35 805-009-35 808-031-25 808-033-35 808-039-35 808-037-35 808-037-02 808-037-03 808-039-02 808-040-25 808-041-35 808-042-35	Otoscope Handles, VISIO 2000.	For Examination of Ear	1	5 and 13	896110278 OTOVIS808 6A	12849 / Z12021007
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**Accessories for Otoscope**

1	NOVA / PRIMA/ VISIO 1500	808-201-25 808-202-35 808-203-45 808-204-55 808-205-90 808-200-03 808-200-04 808-200-05 808-250-01	Reusable Specula No.1 to 5 Set of 3 Specula, No.1 to 3 Set of 4 Specula No. 1 to 4 Set of 5 Specula No. 1 to 5 Reusable Nasal Specula	For Examination of Ear	1	5	896110278 ACCES808 P4	L149004
2	NOVA / PRIMA/ OMNI/ NeuVU/VISIO V-Max/ 5/2000	808-213-25 808-214-40 808-211-25 808-212-40 808-217-07 808-217-01 808-217-00 808-215-25 808-216-40 808-244-01 808-244-02	Disposable Ear Tip Dia 2.5mm & 4.00mm.  Dispenser for Disposable Ear Tips  Metal Adaptor for Disposable Ear tip.	For Examination of Ear	1	5	896110278 ACCES808 P4	L149004
3	VISIO V-Max/ 5/2000	808-206-25 808-207-30 808-208-40 808-209-50 808-210-10 808-206-05	Reusable Specula Dia 2.5mm, 3.0mm, 4.00mm, 5.00mm & 10.0mm	For Examination of Ear	1	5	896110278 ACCES808 P4	L149004

**Spare Lamps**

1	NOVA / PRIMA	833-009-25	Bulbs for Otoscope	-	-	-	896110278 LAMP833 LZ	-
2	OMNI 3000 / NeuVU	833-033-25 833-068-25	Bulbs for Otoscope	-	-	-	896110278 LAMP833 LZ	-
3	VISIO 5 / 2000 / 1500 / V Max	833-013-25 833-033-25 833-015-35 833-070-35	Bulbs for Otoscope	-	-	-	896110278 LAMP833 LZ	-
4	NeuVU	833-083-25	LED for Otoscope	-	-	-	896110278 LAMP833 LZ	-
5	VISIO	833-061-25 833-063-35	LED for Otoscope	-	-	-	896110278 LAMP833 LZ	-