

EU DECLARATION OF CONFORMITY

1. Document No.: PML/MD/DOC/1.12, Rev. 00
2. This declaration of conformity is issued under the sole responsibility of the Poly Medicure Limited.
3. **Address of manufacturing site:** Plot No. 104-105, Sector-59, HSIIDC Industrial Area, Ballabgarh, Faridabad, Haryana-121004, INDIA, info@polymedicure.com.
4. **European Authorized Representative:** Obelis S.A, Boulevard Général Wahis 53, 1030, Brussels, Belgium, regulatory@obelis.net SRN: BE-AR-000000106.
5. **CE Certificate number:** G10 041938 0011, Rev.00, Valid upto: 23.02.2030
6. **Product Name:** Nasogastric Feeding tubes with/without guidewires (Single & Dual port)/Levin's Tube
7. **Product Code and Variants:** Please refer attached Annexure-1.
8. **Intended purpose of device:** Nasogastric feeding tube (Levin's tube) is used for gastro-intestinal feeding and aspiration of intestinal secretions. Nasogastric feeding tube (Levin's tube) is a tube that is inserted through the nose into the upper alimentary canal and is used to facilitate intestinal decompression.
9. The device Nasogastric Feeding Tubes with/without guidewires (Single & Dual port)/ Levin's Tube complies with the General Safety and Performance Requirement (Annexure-I) of European Medical Device Regulation 2017/745.
10. Conformity Assessment Procedure: Annexure-IX, Chapter I & III
11. **SRN:** IN-MF-0000043009
12. **Basic UDI:** 890209540302EJ
13. **MDN Code:** 1201
14. **EMDN Code:** G020299
15. **Reference National / International Standard:** EN ISO 13485:2016/ A11:2021, EN ISO 14971:2019/ A11:2021, EN ISO 15223-1:2021, EN ISO 11135:2014/A1:2019, EN ISO 11607-1:2020/ A1:2023, EN ISO 11607-2:2020/ A1:2023, EN ISO 11737-1:2018 / A1:2021, EN ISO 11737-2:2020, ISO 10993-1:2020, ISO 11138-2:2017, EN ISO 20695:2020, ISO 20417:2021, ISO 11138-1:2017, EN ISO 20695:2020, ISO 80369-2:2024, ISO 2859-1:1999/Amd 1:2011, ISO 14644-1:2015 EN 868-5:2018.
16. **Device Class:** Class IIa, Rule 5
17. The company and its authorized representative shall fulfil the obligations imposed by European Medical Device Regulation 2017/745 & ensure that the product shall meet all provisions as applicable.
18. **Notified Body:** 'TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany', Notified Body No.-0123.

Date of Issue: 02.04.2025

Attachment: Annexure-1



Authorized Signatory
RD Sharma
GM - CQRA & PRRC
On behalf of POLY MEDICURE LIMITED

ANNEXURE-1

S. No.	Polymed Code	Pennine Code	Device Description
1.	40301	AEXLT2206	Nasogastric/Duodenal Access/Aspiration Tube, Levins, Graduated, Xray, 6fg x 125cm, with open tip, four side eyes
2.	40302	AEXLT2208	Nasogastric/Duodenal Access/Aspiration Tube, Levins, Graduated, Xray, 8fg x 125cm, with open tip, four side eyes
3.	40303	AEXLT2210	Nasogastric/Duodenal Access/Aspiration Tube, Levins, Graduated, Xray, 10fg x 125cm, with open tip, four side eyes
4.	40304	AEXLT2212	Nasogastric/Duodenal Access/Aspiration Tube, Levins, Graduated, Xray, 12fg x 125cm, with open tip, four side eyes
5.	40305	AEXLT2214	Nasogastric/Duodenal Access/Aspiration Tube, Levins, Graduated, Xray, 14fg x 125cm, with open tip, four side eyes
6.	40306	AEXLT2216	Nasogastric/Duodenal Access/Aspiration Tube, Levins, Graduated, Xray, 16fg x 125cm, with open tip, four side eyes
7.	40307	AEXLT2218	Nasogastric/Duodenal Access/Aspiration Tube, Levins, Graduated, Xray, 18fg x 125cm, with open tip, four side eyes
8.	40308	AEXLT2220	Nasogastric/Duodenal Access/Aspiration Tube, Levins, Graduated, Xray, 20fg x 125cm, with open tip, four side eyes
9.	40342	AEXLT2406EF	Levins/Feeding Nasogastric Tube - 122cms - 6fg-PU
10.	40343	AEXLT2408EF	Levins/Feeding Nasogastric Tube - 122cms - 8fg-PU
11.	40344	AEXLT2410EF	Levins/Feeding Nasogastric Tube - 122cms - 10fg-PU
12.	40345	AEXLT2412EF	Levins/Feeding Nasogastric Tube - 122cms - 12fg-PU
13.	40346	AEXLT2414EF	Levins/Feeding Nasogastric Tube - 122cms - 14fg-PU
14.	40347	AEXLT2416EF	Levins/Feeding Nasogastric Tube - 122cms - 16fg-PU