

**EU DECLARATION OF CONFORMITY**

1. Document No.: PML/MD/DOC/1.11, 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](mailto:info@polymedicure.com).
4. **European Authorized Representative:** Obelis S.A, Boulevard Général Wahis 53, 1030, Brussels, Belgium, [regulatory@obelis.net](mailto:regulatory@obelis.net) SRN: BE-AR-000000106.
5. **CE Certificate number:** G10 041938 0011, Rev.00, Valid upto: 23.02.2030
6. **Product Name:** Ryle's Tube
7. **Product Code and Variants:** Please refer attached Annexure-1.
8. **Intended purpose of device:** The product is designed to provide access to nasogastric tract for introduction of nutrition and aspiration of intestinal secretion.
9. The device Ryle'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:** 890209540002E3
13. **MDN Code:** 1201
14. **EMDN Code:** G02020101
15. **Reference National / International Standard:**  
**Harmonized Standards:** 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 10993-1:2018, , ISO 11138-2:2017.  
**Non-Harmonized Standards:** 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, as per 2nd indent of 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: 17.03.2025

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.	40015	RT-2108	RYLES TUBE 8FG 122CMS MTL TIP PENNINE
2.	40016	RT-2110	RYLES TUBE 10FG 122CMS MTL TIP PENNINE
3.	40017	RT-2112	RYLES TUBE 12FG 122CMS MTL TIP PENNINE
4.	40018	RT-2114	RYLES TUBE 14FG 122CMS MTL TIP PENNINE
5.	40019	RT-2116	RYLES TUBE 16FG 122CMS MTL TIP PENNINE
6.	40020	RT-2118	RYLES TUBE 18FG 122CMS MTL TIP PENNINE
7.	40001	AERT2306	Nasogastric Access/Aspiration Tube, Ryles, Graduated, Xray, 6fg x 105cm, with Opaque Xray closed tip, four side eyes, with Luer
8.	40002	AERT2308	Nasogastric Access/Aspiration Tube, Ryles, Graduated, Xray, 8fg x 105cm, with Opaque Xray closed tip, four side eyes, with Luer
9.	40003	AERT2310	Nasogastric Access/Aspiration Tube, Ryles, Graduated, Xray, 10fg x 105cm, with Opaque Xray closed tip, four side eyes, with Luer
10.	40004	AERT2312	Nasogastric Access/Aspiration Tube, Ryles, Graduated, Xray, 12fg x 105cm, with Opaque Xray closed tip, four side eyes, with Luer
11.	40005	AERT2314	Nasogastric Access/Aspiration Tube, Ryles, Graduated, Xray, 14fg x 105cm, with Opaque Xray closed tip, four side eyes, with Luer
12.	40006	AERT2316	Nasogastric Access/Aspiration Tube, Ryles, Graduated, Xray, 16fg x 105cm, with Opaque Xray closed tip, four side eyes, with Luer
13.	40007	AERT2318	Nasogastric Access/Aspiration Tube, Ryles, Graduated, Xray, 18fg x 105cm, with Opaque Xray closed tip, four side eyes, with Luer
14.	40008	AERT2320	Nasogastric Access/Aspiration Graduated Xray 20fg x 105cm with Opaque Xray closed tip four side eyes with Luer
15.	40022	AERT2306EF	Nasogastric Feeding Tube, Ryles, Graduated, Xray, with ENFit Connectors, 6fg x 105cm, with Opaque Xray closed tip, four side eyes
16.	40023	AERT2308EF	Nasogastric Feeding Tube, Ryles, Graduated, Xray, with ENFit Connectors, 8fg x 105cm, with Opaque Xray closed tip, four side eyes
17.	40024	AERT2310EF	Nasogastric Feeding Tube, Ryles, Graduated, Xray, with ENFit Connectors, 10fg x 105cm, with Opaque Xray closed tip, four side eyes
18.	40025	AERT2312EF	Nasogastric Feeding Tube, Ryles, Graduated, Xray, with ENFit Connectors, 12fg x 105cm, with Opaque Xray closed tip, four side eyes
19.	40026	AERT2314EF	Nasogastric Feeding Tube, Ryles, Graduated, Xray, with ENFit Connectors, 14fg x 105cm, with Opaque Xray closed tip, four side eyes
20.	40027	AERT2316EF	Nasogastric Feeding Tube, Ryles, Graduated, Xray, with ENFit Connectors, 16fg x 105cm, with Opaque Xray closed tip, four side eyes
21.	40028	AERT2318EF	Nasogastric Feeding Tube, Ryles, Graduated, Xray, with ENFit Connectors, 18fg x 105cm, with Opaque Xray closed tip, four side eyes