Declaration of Conformity for Amnicot

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Device as transposed into European national law by the member states:

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Amnicot
Legal Manufacturer (Name of the Label):	Go Medical Industries Pty Ltd, 200 Churchill Avenue, Subiaco, WA, 6008, Australia
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	The Amnicot is a single-use fingercot designed for performing amniotomies (artificial rupture of amniotic membrane).
MD Directive Classification:	Class II(a)
Notified Body:	BSI - 2797
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta
Medical Device Directive Assessment Route:	EC Declaration by the Notified Body to Annex II (excluding Section 4) of the Medical Device Directive

Name: Dr. George O'Neil **Position:** Medical Director

Signed:  **Date:** 27th November 2023

Who is the natural and legal person with responsibility for design, manufacture, packaging and labelling before the device is placed on the market under the manufacturer's name regardless of whether these operations are carried out by the manufacture or on his behalf by a third party.

GO MEDICAL INDUSTRIES PTY LTD • ABN 99 009 018 339
200 Churchill Avenue, Subiaco, Western Australia • Tel: +61 8 9388 1700 • Fax: +61 8 9382 4952
Email: info@gomedical.com.au • Website: www.gomedical.com.au

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2:2013	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
ISO 11137-3:2017	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code or UMDNS Code
ACD01-E	Amnicot (English)	GMDM: 12990
ACD01-G	Amnicot (German)	
ACD01-P	Amnicot (Polish)	

Version History

Version	Complied by	Date	Description
1.0	M.Vadala	26-Sep-2017	Updated to comply with current EU requirements
2.0	Carly Hardy	6-Dec-2019	Update to new BSI Netherlands and Advena Malta
3.0	J. Lasinger	12-Feb-2021	Updated EN and EN ISO standard versions
4.0	C, Chan	12-Feb-2022	Update applicable standards table
5.0	C, Chan	27-Nov-2023	Update to 2023 issue

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