EC Declaration of Conformity – Article 12 Procedure Packs

Manufacturers Name:	Andersen Caledonia Limited
Manufacturers Address:	Caledonian House, Phoenix Crescent, Strathclyde Business Park Bellshill, North Lanarkshire, Scotland ML4 3NJ
Name of the Device*(s)*:	Sterile Procedure Packs
Product Code:	See Appendix 1
Notified Body name:	SGS Belgium NV
Notified Body Address:	SGS House, Borderland 87, 2030 Antwerp, Belgium
Notified Body Identification Number:	CE 1639
Certificate Number:	GB19/964735 (MDD 93/42/EEC) extension letter reference: CLNB1639 GBPC6743
European Representative	International Associates Auditing & Certification Limited The Black Church, St Mary's Place, Dublin 7, D07 P4AX Ireland EUAR@ie.ia-net.com
Swiss Authorised Representative (SAR)	Best Care Consulting GmbH Kehlhofrain 12a, CH – 6043, Adligenswil ar@ch-rep.com
Conformity Assessment Route:	Andersen Caledonia Ltd. uses the following procedures for the CE Marking of their products according to the Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC

Article 12 Sterile Procedure Packs

Andersen Caledonia Ltd. hereby declare that the medical devices used within the Sterile Procedure Packs specified in Appendix 1 of this document are mutually compatible when these are used in accordance with the manufacturer's instructions / indications.
The medical devices used within the Sterile Procedure Packs have been packaged and sterilised in accordance to the manufacturer's instruction by Andersen Caledonia Ltd.
This has been carried out under a Quality Management System which complies with the requirements of Annex V of the Medical Device Directive 93/42/EEC
We hereby declare that the Sterile Procedure Packs specified in Appendix 1 meets with and conforms to the Essential Requirements of the Medical Device Directive 93/42/EEC (June 14, 1993) as amended by Directive 2007/47/EC (Sept, 21 2007).
Andersen Caledonia Ltd follows Annex V Production Quality Assurance under supervision of SGS Belgium NV (NB 1639) in addition we also maintain a Quality Management System in accordance with ISO 13485:2016 / EN ISO 13485:2016 (GB18/873806) issued by SGS UK Ltd, Inward Way, Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK.

All supporting documentation is retained at the premises of the manufacturer.

Approved By	**Signature**	**Date**
Jonathan Lintott Managing Director		27th March 2024

Appendix 1

Product Code	Description	GMDN	EMDN	UDI
MP003-PP001-04	Hysteroscopy Packs	37552	V9016	5060544341422
MP005-PP004-07	IUD Pack	60644	V9016	5060544341583
MP005-PP004-08	IUD Pack	60644	V9016	5060544341590
MP005-PP004-09	IUD Pack	60644	V9016	5060544341606
MP005-PP004-10	IUD Pack	60644	V9016	5060544341613
MP005-PP004-11	IUD Pack	60644	V9016	5060544341620