Declaration of Conformity

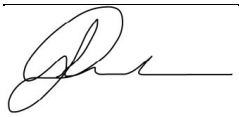
for the TelScope Telehealth and ThroatScope Systems

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	TelScope Telehealth & ThroatScope Systems
Legal Manufacturer: (Name on Label)	Throat Scope Pty Ltd Level 25, 123 Eagle St., Brisbane QLD 4000, Australia
Manufacturers SRN:	AU-MF-000025190
Basic UDI-DI:	859523006001GC
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Visualisation of oral cavity.
MDR Classification:	Class I according to rule 5, Annex VIII of Medical Device Regulations
Notified Body:	Not Applicable
EC Certificate:	N/A
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	**MT-AR-000000234**
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name Jennifer Holland **Position** CEO

Signed  **Date** 28 June 2022 **Place** Australia

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

Appendix I – Applicable Standards

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

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer

Appendix II – Product Listing/Schedule

Catalogue Number / UDI-DI	Device Name	EMDN Code
TEL 100	TelScope single handle	V9001
TEL100x48	Tel Scope shipper (48 Singles)	V9001
TS102	ThroatScope Tongue Depressor (pack of 50)	V9001
10PACK	Pack of 10 Tongue Depressors	V9001
HH106	ThroatScope Handle x 1	V9001
TSH102	Throat Scope Handle plus 50 depressors	V9001

Version History

Version	Compiled by	Date	Description
1	D Broderick	25th Oct 2020	Initial Issue
2	D Broderick	25th May 2021	MDR Update
3	D Broderick	10th Feb 2022	Change EUAR from Emergo to Advena
4	D Broderick	27th Feb 2022	Merge ThroatScope and Telscope DoCs and new format DoC
5	D Broderick	28 June 2022	Addition of SRN