Manufacturer	
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*. The EU declaration of conformity contains the information set out in *Annex IV of REGULATION (EU) 2017/745.*	
Manufacturer's name and address	**TensCare Ltd** 9 Blenheim Road, Epsom, Surrey KT19 9BEUnited Kingdom Tel + 44 1372 723434, www.tenscare.co.uk
Single Registration No	GB-MF-000004156
Authorised Representative name and address	**Advena Ltd** Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013, Malta
Single Registration No	MT-AR-000000234

Product	
Product name	**Liberty Probe, Liberty Plus Probe**
BASIC UDI	5033435E00026X2
Intended Purpose	The probes are intended for the treatment of stress, urge and mixed urinary incontinence and the treatment of pelvic pain in women.
Risk Class	IIa
MDR Classification	Rule 5 in Chapter III of Annex VIII of the REGULATION (EU) 2017/745
Photo of product (including image of bar code)	
EMDN Code (CND Code)	N010201 Probe (invasive electrode)
GMDN	36050 Probe (invasive electrode)

Statement:
We, the manufacturer, herewith declare that the products 'Liberty Probe' and 'Liberty Plus Probe' meet the provisions of REGULATION (EU) 2017/745 which apply to it. The medical device has been assigned to class IIa according to Annex VIII of the REGULATION (EU) 2017/745. The product concerned has been designed and manufactured under a quality management system according to Annex IX chapters I and III, of REGULATION (EU) 2017/745. This EU declaration of conformity is issued under the sole responsibility of the manufacturer. No "Common Specification" is applicable.

Notified Body	
Notified Body and Address	BSI Netherlands BSI Netherlands. B.V., John M. Keynesplein 9, 1006 EP Amsterdam, The Netherlands
Identification No	CE 2797
Conformity Assessment route	*In conformity with Article 52(6) of Regulation (EU) 2017/745, Annex IX (Chapters I and III), with assessment of the technical documentation for at least one representative device for each category of devices*
Certificates: CE	MDR 745087
EN13485:2016	MD720662

Signed on behalf of TensCare Ltd by: Raluca Constantinescu 	**Position:** Quality & Regulatory Executive / PRRC
Place: Epsom, UK	**Date:** 07/10/2025

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	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	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
EN60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN60601-1-11	Amendment 1 – Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN60601-2-10	Particular Requirements for the basic safety and essential performance of nerve and muscle stimulators
Applicable requirements of Directive 2011/65/EU (RoHS2)	*The restriction of the use of certain hazardous substances in electrical and electronic equipment*

Appendix II – Product Listing/Schedule

UDI-DI	Product Code	Device Name	Catalogue Number
05033435000593	X-VP	Liberty Probe	X-VP
05033435130610	X-VPM	Liberty Plus Probe	X-VPM

Revision History

Revision	Compiled by	Date	Description of changes
1.1	Saskia Eldridge-Hinmers	12/07/2023	Merged DoC created for all vaginal Liberty probes
2.1	Raluca Constantinescu	02/02/2024	Updated to individual DoC for Liberty Loop probe (match MDR mandate)
3.1	Saskia Eldridge-Hinmers	22/07/2024	New template for Class IIa devices
3.2	Raluca Constantinescu	22/08/2024	Catalogue number updated, full document history added
3.3	Raluca Constantinescu	19/09/2024	iTouch Go probe added

3.4	Raluca Constantinescu	26/05/2025	iTouch Go probe removed
3.5	Raluca Constantinescu	07/10/2025	Template changed to include MDR assessment route