EU Declaration of Conformity

Manufacturer	
The EU declaration of conformity is issued under the sole responsibility of the manufacturer. The EU declaration of conformity contains the information set out in ANNEX V of COUNCIL DIRECTIVE 93/42/EEC.	
Manufacturers name and address	**TensCare Ltd** 9 Blenheim Road, Epsom, Surrey KT19 9BE United Kingdom Tel + 44 1372 723434, www.tenscare.co.uk
Single Registration No	TBC
Authorised Representative name and address	**Advena Ltd** Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013, Malta

Product								
UDI -DI	05033435135851							
Product name	Mynd							
Product code	K-MYND							
Catalogue number	**New:** K00139 **Previous:** K-MYND							
Intended Purpose	MYND is a medical device designed to be used in the home healthcare environment for the treatment and prevention of frequent episodic and chronic migraine headaches. It is suitable for use by all who can control the device and understand the instructions. It may be used by a child from the age of 8 if supervised by an adult, but there is currently no evidence of effectiveness for users under the age of 18. This device is only used for forehead surface skin. Do not use the device for any purpose other than this intended use.							
CND Code	Z120622 TENS	X	Z12062801 EMS		U0703 Continence		N010201 Probe (invasive electrode)	
GMDN	35372 TENS	X	46573 EMS		65013 Continence		36050 Probe (invasive electrode)	
Risk Class	IIa							
Applicable Harmonised Standards specific to this product	We certify that this product complies with the requirements of the current harmonized version of EN60601-1, EN60601-1-2, EN60601-1-11, EN60601-2-10 and with the applicable requirements of Directive 201 1/65/EU (RoHS2)							

Statement:
We, the manufacturer, herewith declare that the product Mynd meets the provisions of Directive 93/42/EEC which apply to it. The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC and Directive 2011/65/EU. This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Notified Body	
Notified Body	BSI Netherlands
Identification No	CE 2797
Conformity Assessment route	Annex V of the Medical Devices Directive 93/42/EEC
Certificates: CE	CE720664
EN13485:2016	MD720662

Signed on behalf of TensCare Ltd by:	**Position:** Quality and Regulatory Affairs Manager
Place: Epsom, UK	**Date:** 16/02/2021

REVISION HISTORY			
Revision	**Date**	**Description of Changes**	**Reason for Change**
1	13/10/2020	New Form created for EU DoC	MDR
2	16/02/2021	Updates to GMDN codes as these have changed and updates to CND codes to meet MDR REGULATION (EU) 2017/745.	Change in GMDN and CND codes.