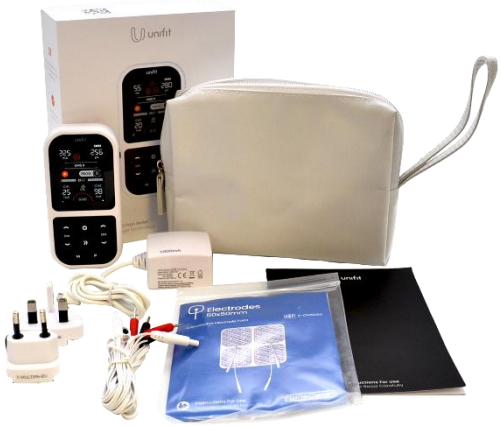
Manufacturer	
The EU declaration of conformity is issued under the sole responsibility of the manufacturer. The EU declaration of conformity contains the information set out in *Annex IV of REGULATION (EU) 2017/745 or ANNEX V of COUNCIL DIRECTIVE 93/42/EEC*.	
Manufacturers name and address	**TensCare Ltd** 9 Blenheim Road, Epsom, Surrey KT19 9BE United Kingdom Tel + 44 1372 723434, www.tenscare.co.uk
Single Registration No	GB-MF-000004156
Authorised Representative name and address	**Advena Ltd** Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013, Malta

Product		
	Device only	*Procedure Pack*
BASIC UDI	*5033435K00176DTA*	*5033435K0017627*
UDI -DI	*5033435136999*	*05033435136209*
Product name	***Unifit***	
Product code	*K-UNIFIT*	
Photo of product (including image of bar code)	 *Procedure Pack* *UDI+DI+PI* UDI (01) 0 5033435 13620 9 (21) 1220071389	
Catalogue number	**New:** K00176	**Previous:** K-UNIFIT

Intended Purpose	Unifit combines the treatment capabilities of a TENS device, an EMS or NMES device, and a relaxing massage stimulator in one unit. Unifit is a medical device designed to be used in the home healthcare environment to improve muscle tone and bulk, as well as provide symptomatic relief and management of acute or chronic localised pain and muscle pain. It is suitable for use by all who can control the device and understand the instructions.							
CND Code	Z120622 TENS	X	Z12062801 EMS	X	U0703 Continence		N010201 Probe (invasive electrode)	
GMDN	35372 TENS	X	46573 EMS	X	65013 Continence		36050 Probe (invasive electrode)	
	46573 Physical therapy transcutaneous neuromuscular electrical stimulation system	X						
Risk Class	IIa							
Applicable latest revisions of key 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 **Unifit** meets the provisions of REGULATION (EU) 2017/745 which apply to it. The medical device has been assigned to class IIa according to Annex IV of the REGULATION (EU) 2017/745. The product concerned has been designed and manufactured under a quality management system according to Annex IX, 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	BSI Netherlands
Identification No	CE 2797

Conformity Assessment route	*Annex IX, of REGULATION (EU) 2017/745*
Certificates: CE	MDR745087
EN13485:2016	MD720662

Signed on behalf of TensCare Ltd by:  Saskia Eldridge-Hinmers	**Position:** Quality Assurance & Regulatory Affairs Executive / PRRC
Place: Epsom, Surrey, UK	**Date:** 07/07/2023