



EC Declaration of Conformity

Manufacturer: TOP-RANK Health Care Co., Ltd

Whose single Authorized Representative:

Address: Checun Village, Dongguan Street, Shangyu District, Shaoxing City, Zhejiang Province, P. R. China.

Shanghai International Holding Corp. GmbH (Europe)

Address:Eiffestrasse 80, 20537 Hamburg, Germany

WE, AS THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

HEREWITH DECLARE THAT /

the STATE medical device: /

Adhesive Electrodes

Model: /

See Appendix 1

Intended purpose: /

Adhesive Electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Adhesive Electrodes are intended to be used with marketed Electrical Stimulators, i.e. TENS and EMS. It is for OTC use.

Basic UDI-DI: /

697360273ELECTRODESHX

CND Code: /

N010201 TENS SYSTEM ELECTRODES

Of class: /

I, RULE 1 (4.1) according to Annex VIII of Regulation EU 2017/745(MDR)

Applicable harmonized standards are: /

EN 1041; EN ISO 15223-1; EN ISO 14971; EN ISO 10993-1; EN ISO 10993-5; EN ISO 10993-10; EN ISO 10993-12; EN MEDDEV 2.7/1; EN 62366-1; EN ISO 13485; MEDDEV 2.12/1 Rev 8; MEDDEV 2.12/2 Rev 2; MDR (EU) 2017/745; EN 60601-1; EN 60601-1-2; EN 60601-1-6; EN 60601-2-10.

Conformity assessment procedure: /

Declare the conformity of the abovementioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745 / according to Article 52(7) of Regulation (EU) 2017/745 /

Meets the provisions of the Regulation (EU) 2017/745 which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

Shaoxing 2021/4/21

Xiangwen Zhou/ Management representative

Ort, Datum / Place, date /

Name und Funktion / Name and function /

Lieu, date / Luogo, data

Nom et fonction / Nome e funzione



Appendix 1:Electrodes Model:

Table 1.1 Adhesive Electrodes

Product Name	Type		
Square shape	CM3939	CM4040	CM4545
	CM4646	CM4848	CM5050
	CM5353	CM5555	CM5959
	CM6060	CM6565	CM7070
	CM8080	CM9090	CM100100
Rectangle shape	CM1427	CM1452	CM1823
	CM2839	CM3050	CM3845
	CM3954	CM4060	CM4080
	CM4090	CM40100	CM40150
	CM40350	CM4464	CM4550
	CM4560	CM4580	CM4595
	CM45110	CM13088	CM16699.
	CM4668	CM4798	CM4875
	CM4972	CM4987	CM5053
	CM5056	CM5060	CM5078
	CM5080	CM5090	CM50100
	CM50130	CM50135	CM5350
	CM5370	CM5380	CM5394
	CM5590	CM57106	CM5995
	CM6040	CM6090	CM6498
	CM65101	CM69110	CM70120
	CM70130	CM71110	CM72107
	CM75100	CM75104	CM75130
	CM75150	CM80120	CM80130
	CM90130	CM93150	CM9457
	CM9840	CM100125	CM100150
	CM100200	CM110150	CM110190
	CM120180	CM13040	CM13088
CM16699	CM7286	CM7584	
CM26121	CM64112		
Round shape	CM18D	CM20D	CM22D
	CM25D	CM28D	CD30D
	CM32D	CM35D	CM40D
	CM45D	CM50D	CM55D
	CM60D	CM65D	CM70D
	CM75D	CM80D	CM85D
	CM90D	CM95D	CM100D



	CM110D	CM120D	CM150D
	CM170D		
Oval shape	CM4060V	CM4972V	CM5080V
	CM5090V	CM50100V	CM50105V
	CM50130V	CM6080V	CM6090V
	CM70100V	CM70110V	CM70120V
	CM75130V	CM80130V	CM90130V
Special shape	CM3050T	CM40130T	CM4875T
	CM5078T	CM60130T	CM93150T
	CM110150T	CM13040T	CM13088T
	CM16699T		
With handle shape	CM4040ES	CM4080ES	CM40130ES
	CM4595ES	CM4646ES	CM4848ES
	CM5050ES	CM5060ES	CM5078ES
	CM5090ES	CM5252ES	CM6060ES
	CM6090ES	CM6498ES	CM6498ES
	CM80120ES	CM9840ES	CM16699ES
	CM32DES	CM35DES	CM40DES
	CM45DES	CM50DES	CM60DES
	CM70DES	CM75DES	CM80DES