Dillenburg Medical

EU Declaration of Conformity

according to Annex IV of (EU) MDR 2017/745

Dillenburg Medical B.V.
Otterkoog 20-j
1822 BW Alkmaar / NL

SRN: NL-MF-000006104

herewith declares under its sole responsibility, that the products

Stadtholder® Gel hot/cold packs with

Basic UDI (GMN): 8719274GELPACK59

Item number	Description	GTIN
101004	12x29cm	08719274280866
101007	16x26cm	08719274281467
101016	16x26cm / 6 pcs.	08719274281542
101008	20x34cm	08719274281603
101009	30x40cm	08719274281474

meet with the Regulations of (EU) MDR 2017/745
(Annex VIII, Chapter III, Section 4.1, Rule 1, Non-Invasive Devices)

meet with the requirements according to Regulations (EU) 2017/745,
Annex I, General safety and performance
Annex II, Technical Documentation

References

DIN EN ISO 14971:2020	DIN EN ISO 10993-10:2014
DIN EN ISO 15223:2017	DIN EN 1041:2013
DIN EN ISO 10993-1:2010	DIN EN ISO 9000:2015
DIN EN ISO 10993-3:2015	DIN EN 9001:2015
DIN EN ISO 10993-5:2009	

Risk Class: above referenced products are Class I products.

Validity: this Declaration of Conformity is valid until 01-08-2024

Place/Date : Alkmaar, 01 June 2022

Signature R. Troost, QM, Dillenburg Medical B.V. :