



EG – Konformitätserklärung EC – Declaration of Conformity CE - La déclaration de conformité

Date
Day / Month / Year
29.07.2022

Tetcon Global BV

Ruysdaelbaan 3G 5642 JJ Eindhoven The Netherlands

declares, solely responsible, that the medical devices and its accessory

S-CAPEPOD Evacuation Sheets

Model: Standard Model (Art. Nr. 5N88888813), Budget Model 80-90 cm (Art. Nr. 50832100AZ), Budget Model 91-105 cm (Art. Nr. 50832100BM), Bariatric Model (Art. Nr. 5N88888812)

meet all the provisions of the regulation MDR 2017/745/EU of the European Parliament and of the council of 5 April 2017 on medical devices (MDR), which apply to him.

The product is classified in Class 1 according to Regulation MDR 2017/745/EU.

Applied standards:

NEN-EN-ISO 13485:2016 EN NEN-EN-ISO 14971:2019 EN

Basic UDI-DI: 8720726730S-CAPEPOD9U

GMDN: 65516

Corresponding technical documentation and quality manual is available for examination.

Eindhoven, 29.07.2022 Place, Date TETCON GLOBAL BV
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Signed by Tetcon management and representative: Bob Hezemans