



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

Date
Day / Month / Year
10.04.2021

Tetcon Global BV

Ruysdaelbaan 3G 5642 JJ Eindhoven The Netherlands

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

Retmex Rescue Sheets

Models: Comfort Model (Art. Nr. 10PVC76590), Compact Model (Art. Nr. 1099876610), Nomex Model (Art. Nr. 1099602001), Bariatric Model (Art. Nr. 109960219)

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

Corresponding technical documentation and quality manual is available for examination.

Eindhoven, 17.04.2021 Place, Date TETCON GLOBAL BV Ruysdaelbaan 3G 5642 JJ Eindhoven (NL) +31 (0) 40-2989955 info@tetcon-ge.com

Signed by Tetcon management and representative: Bob Hezemans