

	EG – Konformitätserklärung EC – Declaration of Conformity CE - La déclaration de conformité	Date Day / Month / Year 29.07.2022
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Tetcon Global BV
 Ruysdaelbaan 3G
 5642 JJ Eindhoven
 The Netherlands

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

UltraSlider ICU Fitted Sheets

Models: UltraSlider Fitted Sheet – IC Model (95 x 220 x 24 cm - Art. Nr. 60952200BR) (92 x 212 x 16 cm – Art. Nr. 6009221216), UltraSlider Fitted Sheets – HC Model (Art. Nr. 6095220KOP), UltraSlider Flat Sheet (Single Layer) (150 x 100 cm – Art. Nr. 60150100UL) (150 x 66 cm – 6015066ULT)

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

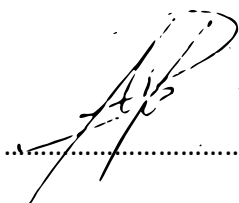
Basic UDI-Di: 8720726730UltraSlider72

GMDN: 37163

Corresponding technical documentation and quality manual is available for examination.

Eindhoven, 29.07.2022

Place, Date



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Signed by Tetcon management and representative: Bob Hezemans