

QUALITY CERTIFICATE Certificate of Sterilization (CoS)

Ref: 10605174 - Catheterisation set req 743

Batch: 2410196

Expiry date: 2027-05

This is certifying that the above-mentioned product has been primarily sterilized by Ethylene Oxide (EO) within a sterilization cycle development/validation performed to 10^{-6} SAL in accordance with current ISO 11135 guidelines.

Sterisets Manufacturing S.A. further certifies that the above batch of production has been manufactured in compliance with Council Directive 93/42/EEC, Portuguese Law through the Decreto-Lei no. 145/2009 and the applicable requirements of EN ISO 13485:2016.

Quality Department

Joana Pinto

28/11/2024

Sterisets Manufacturing S.A.

Zona Industrial 1 – Lote 34 a 35, 4560-164 Guilhufe, Penafiel PORTUGAL

Phone: +31 412 236 606

www.sterisets.com

PART OF STI GROUP

