

QUALITY CERTIFICATE Certificate of Sterilization (CoS)

Ref: 10606074 - Dialysis start set

Batch: 2410200

Expiry date: 2029-10

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

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