



DECLARATION OF CONFORMITY TO THE DIRECTIVE 93/42/EEC and s.m.i.

Concerning medical devices

MEDICAL DEVICE CLASS I



I, the undersigned Giovanni Scalabrini, being the legal representative of SCALABROS SRL, via Caduti di Sabbiano 83/C – 40053 VALSAMOGGIA (BO). Tel: 051-832587 – E-mail: info@scalabros.it - C.F. 02853661201

DECLARE

under my own responsibility

that the **DISPOSABLE SHOE COVER / ELASTIC OVERSHOE model CZ.001.001**

classification CND - **T0208**

- complies with Directive 93/42/EEC
- is designed and manufactured according to Quality Assurance System conforming to the requirements of Annex VII of the Directive.
- complies with harmonised standard - EN 13795-1:2019 *regarding the applicable performance requirements.*

The person responsible to keep all the Technical Documentation is Benedetto Scalabrini at the headquarters of SCALABROS.

Valsamoggia (BO) Italy, 31/07/2020

Stamp and Signature

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