## SCALABROS SRL



# DECLARATION OF CONFORMITY TO THE DIRECTIVE 93/42/EEC e 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 Sabbiuno 83/C - 40053 VALSAMOGGIA (BO). Tel: 051-832587 - E-mail: info@scalabros.it - C.F. 02853661201

#### **DECLARE**

under my own responsibility

### that the SURGICAL DISPOSABLE GOWN model CC.001.001

classification CND - T0204

- 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

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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