

CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

Biosurfit S.A.

Rua 25 de Abril, no. 66

PT - 2050-317 Azambuja



has established and applies a quality management system
for the following scope:

Design, development, manufacture and servicing of a diagnostic point-of-care medical device used for multi parameter testing

Through an Audit, Report No. 7980893010CV15, proof has been furnished that the quality management system fulfils the requirements of the standard

EN ISO 13485:2016

Please refer to the Quality Manual for the details about the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 1080911**.

This Certificate is valid from 2022-07-27 to 2025-07-26.

The reference date for all the next audits is (day-month): 18-06.

Milan, 2022-07-27. First Certification: 2010-07-27

A handwritten signature in blue ink, appearing to read 'Daniele Ricchi', written over a horizontal line.

The certification responsible: Daniele Ricchi
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of the Directives 93/42/EEC, 90/385/EEC, 98/79/EC or Regulations (UE) 2017/745, (UE) 2017/746 have been fulfilled.



SGO N° 083 A



Management System
EN ISO
13485:2016

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ID 9106057539



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Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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