

CERTIFICATE

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

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

BHL MEDICAL - INDÚSTRIA DE PRODUTOS HOSPITALARES, LDA

Estrada da Avessada, n° 390

PT - 2665-402 Santo Estevão Das Galés

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

Manufacture of sterile administration contrast media systems and accessories, sterile high-pressure lines and accessories, sterile irrigation systems and accessories, sterile aspiration systems and sterile perfusion systems and accessories. Manufacture for third party of probe for hystero-graphy, disposables for endometrial and cervical collect samples.

Through an Audit, Report No. 7974622050CN21, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI CEI 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 0371802**.

This Certificate is valid from 2021-12-09 to 2024-12-11.

The reference date for all the next audits is (day-month): 11-07.

Milan, 2021-12-09. First Certification: 2017-11-17

The certification responsible: Cesare Gentile
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 or 98/79/EC have been fulfilled.



SGQ N° 083 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements



Management System
EN ISO
13485:2016

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