

# CERTIFICATE

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

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

**BHL – Medical Industria de Productos  
Hospitalares, LDA**

**Estrada de Avessada, n° 390**

**PT - 2665-402 Santo Estevão Das Galés (Malveira)**

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

**Manufacture, packaging, and storage of administration contrast media systems and accessories, high-pressure lines and accessories, irrigation systems and accessories, aspiration systems and perfusion systems and accessories. Manufacture for third party of register and sliding register for histerography, currettes for suction and abortion, disposables for endometric and cervical collect samples.**

Through an Audit, Report No. 28118476 001, 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 2020-08-31 to 2021-12-11.

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

**Milan, 2020-08-31.** First Certification: 2017-11-17



The certification responsible: Massimiliano Testi  
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20010 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



Management  
System  
EN ISO  
13485:2016

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