

# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
216869-2017-AQ-BRA-NA-PS

Initial certification date:  
18 October 2017

Valid:  
05 November 2025 – 25 February 2028

This is to certify that the management system of  
**INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR  
LTDA.**

Av. Severo Dullius, 1395, 4º andar, sala 403 - Bairro Anchieta, 90200-310, Porto Alegre, RS,  
Brazil

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

**ISO 13485:2016 / EN ISO 13485:2016**

This certificate is valid for the following scope:

**DESIGN, MANUFACTURING, SERVICE, SALES AND DISTRIBUTION OF  
CARDIOVERTERS, DEFIBRILLATORS AND MULTIPARAMETER PATIENT MONITORS.  
IMPORT, DISTRIBUTION AND SALES OF  
ELECTROCARDIOGRAPHS AND CHEST COMPRESSORS.**

Place and date:  
Høvik, 05 November 2025



For the issuing office:  
**DNV Product Assurance AS**  
Veritasveien 1, 1363 Høvik, Norway

*Cecilie Gudesen Torp*

**Cecilie Gudesen Torp**  
Management Representative

## Appendix to Certificate

### INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA.

Locations included in the certification are as follows:

| Site Name                                   | Site Address                                                                                        | Site Scope                                                                                                                                                                               |
|---------------------------------------------|-----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA. | Av. Severo Dullius, 1395, 4° andar, sala 403 - Bairro Anchieta, 90200-310, Porto Alegre, RS, Brazil | DESIGN AND SERVICE OF CARDIOVERTERS, DEFIBRILLATORS AND MULTIPARAMETER PATIENT MONITORS.                                                                                                 |
| INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA. | Rua Albatroz, 237, Cidade Universitária Pedra Branca, 88137-290, Palhoça, SC, Brazil                | MANUFACTURING, SALES AND DISTRIBUTION OF CARDIOVERTERS, DEFIBRILLATORS AND MULTIPARAMETER PATIENT MONITORS. IMPORT, DISTRIBUTION AND SALES OF ELECTROCARDIOGRAPHS AND CHEST COMPRESSORS. |