

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.: 216869-2017-AQ-BRA-NA-PS Initial certification date: 18 October 2017

Valid: 30 April 2024 – 25 February 2025

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

Beco José Paris, 339, Pavilions 18 and 19, Condomínio Empresarial Mont'Serrat - Bairro Sarandi, 91140-310, 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, 30 April 2024





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

Ceutie Gudesen Top

Cecilie Gudesen Torp Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid. ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway - TEL: +47 67 57 99 00. www.dnv.com



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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. | Beco José Paris, 339, Pavilions 18 and 19, Condomínio Empresarial Mont'Serrat - Bairro Sarandi, 91140-310, Porto Alegre, RS, Brazil | DESIGN, MANUFACTURING, SERVICE, SALES AND DISTRIBUTION OF CARDIOVERTERS, DEFIBRILLATORS AND MULTIPARAMETER PATIENT MONITORS. |
| INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA. | Rua Albatroz, 237, Cidade Universitária Pedra Branca, 88137290, Palhoça, SC, Brazil | MANUFACTURING, SALES AND DISTRIBUTION OF DEFIBRILLATORS. IMPORT, DISTRIBUTION AND SALES OF ELECTROCARDIOGRAPHS AND CHEST COMPRESSORS. |

