

EC Certificate Full Quality Assurance System

Certificate No.:
216871-2017-CE-BRA-NA-PS

Project No.:
PRJC-510613-2014-MSL-BRA

Valid until:
08 November 2021

This is to certify that the quality system of:

INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA.

Beco José Paris, 339. Pavilion 19. Condomínio Empresarial Mont'Serrat - Bairro Sarandi, Porto Alegre, RS, 91140-310, Brazil

For design, production and final product inspection/testing of:

Defibrillators

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 25 October 2017



For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift for Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate 201649-2016-CE-BRA-NA following transfer of Notified Body functions to DNV GL Nemko Presafe AS	2017-10-25

Products covered by this Certificate:

Product Description	Product Name	Class
Biphasic Monitor Defibrillator	CARDIOMAX	IIb
Automatic External Defibrillators	ISIS; ISIS PRO; EAZY; EAZY PRO	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Instramed Indústria Médico Hospitalar Ltda.

Beco José Paris, 339. Pavilion 19. Condomínio Empresarial Mont’Serrat - Bairro Sarandi, Porto Alegre, RS, 91140-310, Brazil

EU Representative

OBELIS S. A.

Bd. Général Wahis 53, 1030 Brussels, Belgium

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate