

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
289758-2019-CE-BRA-NS-PS Rev. 0.0

Project No.:
PRJC-531733-2015-MSL-BRA

Valid Until:
27 May 2024

This is to certify that the quality system of:

INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA.

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

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

Has been assessed with respect to:
**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN
ANNEX II EXCLUDING SECTION 4 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, 02 December 2019



For:
DNV GL PRESAFE AS

Notified Body No.: 2460

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Sholeh Gheissar

The certificate is digitally verified by blockchain
technology. For more info, see
www.dnvgl.com/assurance/certificates-in-the-blockchain.html



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

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Jurisdiction

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

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	2019-12-02

Products covered by this Certificate:

Product Description	Product Name	Class
BIPHASIC MONITOR DEFIBRILLATORS	CARDIOMAX DUALMAX	I Ib

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Instramed Indústria Médico Hospitalar Ltda	Beco José Paris, 339. Pavilhão 19. Condomínio Empresarial Mont'Serrat - Bairro Sarandi. Porto Alegre - RS - Brazil. 91140-310.

EU Representative

OBELIS S. A. Bd. Général Wahis 53, B-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