

# 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**

*Sholeh Gheissar*

**Sholeh Gheissar**

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



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

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

Valid Until:  
27 May 2024

**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	IIb

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

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

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

Valid Until:  
27 May 2024

## 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



**Notified Body Confirmation Letter Reference: C656856**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

**INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA**

Beco José Paris, 339, Pavilions 18 and 19, Condomínio Empresarial Mont'Serrat - Bairro Sarandi, Porto Alegre, RS, Brazil, 91140-310

SRN Number (if available): BR-MF-000033452

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:  
Høvik, 2024/03/05



For the issuing office:  
DNV Product Assurance AS – Notified Body 2460  
Veritasveien 1, 1363 Høvik, Norway

André Fernandes  
Management Representative

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer’s continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

<b>Device name and Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD device</b>	<b>MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
AUTOMATIC EXTERNAL DEFIBRILLATORS  i.on  789850904IONXY	Class III	N/A	Certificate Number: 289757-2019-CE-BRA-NA-PS Rev. 0.0  NB Name: DNV Product Assurance AS  NB number: 2460
AUTOMATIC EXTERNAL DEFIBRILLATORS  i.on pro  789850904IONPRO3E	Class III	N/A	Certificate Number: 289757-2019-CE-BRA-NA-PS Rev. 0.0  NB Name: DNV Product Assurance AS  NB number: 2460
AUTOMATIC EXTERNAL DEFIBRILLATORS  CARDIOMAX  789850904CARDIOMAXYT	Class III	N/A	Certificate Number: 289758-2019-CE-BRA-NA-PS Rev. 0.0  NB Name: DNV Product Assurance AS  NB number: 2460

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
AUTOMATIC EXTERNAL DEFIBRILLATORS  DUALMAX  789850904DUALMAX7Z	Class III	N/A	Certificate Number: 289758-2019-CE-BRA-NA-PS Rev. 0.0  NB Name: DNV Product Assurance AS  NB number: 2460

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

### Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/03/05	C656856	Initial issue

### Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.



**Notified Body Confirmation Letter Reference: C656856**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

**INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA**

Beco José Paris, 339, Pavilions 18 and 19, Condomínio Empresarial Mont'Serrat - Bairro Sarandi, Porto Alegre, RS, Brazil, 91140-310

SRN Number (if available): BR-MF-000033452

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:  
Høvik, 2024/03/05



For the issuing office:  
DNV Product Assurance AS – Notified Body 2460  
Veritasveien 1, 1363 Høvik, Norway

André Fernandes  
Management Representative

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer’s continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
AUTOMATIC EXTERNAL DEFIBRILLATORS  i.on  789850904IONXY	Class III	N/A	Certificate Number: 289757-2019-CE-BRA-NA-PS Rev. 0.0  NB Name: DNV Product Assurance AS  NB number: 2460
AUTOMATIC EXTERNAL DEFIBRILLATORS  i.on pro  789850904IONPRO3E	Class III	N/A	Certificate Number: 289757-2019-CE-BRA-NA-PS Rev. 0.0  NB Name: DNV Product Assurance AS  NB number: 2460
AUTOMATIC EXTERNAL DEFIBRILLATORS  CARDIOMAX  789850904CARDIOMAXYT	Class III	N/A	Certificate Number: 289758-2019-CE-BRA-NA-PS Rev. 0.0  NB Name: DNV Product Assurance AS  NB number: 2460



Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
AUTOMATIC EXTERNAL DEFIBRILLATORS  DUALMAX  789850904DUALMAX7Z	Class III	N/A	Certificate Number: 289758-2019-CE-BRA-NA-PS Rev. 0.0  NB Name: DNV Product Assurance AS  NB number: 2460

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

### Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/03/05	C656856	Initial issue

### Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.

# APPENDIX TO EC CERTIFICATE

Certificate no.:  
289758-2019-CE-BRA-NS-PS Rev.0

Valid Until:  
25 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:  
**INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA.**

originally issued in compliance with:  
**the Council Directive 93/42/EEC on Medical Devices, as amended**

Based on assessment and audit performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

Sites covered by certificate (replaces information on certificate)	
Site Name	Site Address
INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA.	Beco José Paris, 339, Pavilions <b>18</b> and 19, Condomínio Empresarial Mont'Serrat - Bairro Sarandi, 91140-310, Porto Alegre, RS, Brazil
INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA.	<b>Rua Albatroz, 237, Cidade Universitária Pedra Branca, 88137290, Palhoça, SC, Brazil</b>

Appendix History -		
Revision	Description	Issued Date
0.0	Admin change: Removal of Norwegian Accreditation	15 December 2021
1.0	Review of company name: added number <b>18</b> in the legal manufacture address. <b>Added manufacture site:</b> <b>Rua Albatroz, 237, Cidade Universitária Pedra Branca, 88137290, Palhoça, SC, Brazil</b>	30 April 2024

Place and date:  
Høvik, 30 April 2024



For the issuing office:  
**DNV Product Assurance AS - Notified Body**  
2460  
Veritasveien 1, 1363 Høvik, Norway



**Hazem Tinawi**  
Technical Reviewer

# APPENDIX TO EC CERTIFICATE

Certificate no.:  
289758-2019-CE-BRA-NA-PS Rev.0

Valid Until:  
25 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:  
**INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA.**

originally issued in compliance with:  
**the Council Directive 93/42/EEC on Medical Devices, as amended**

Based on assessment and/or audit performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

Appendix History -		
Revision	Description	Issued Date
0.0	Admin change: Removal of Norwegian Accreditation	15 December 2021
0.1	Review of company name: added number <b>18</b> in the legal manufacture address. <b>Added manufacture site: Rua Albatroz, 237, Cidade Universitária Pedra Branca, 88137290, Palhoça, SC, Brazil</b>	30 April 2024
0.2	Admin change: Correction of Typo in the Certificate number.	04 July 2024

Place and date:  
Høvik, 04 July 2024



For the issuing office:  
DNV Product Assurance AS - Notified Body  
2460  
Veritasveien 1, 1363 Høvik, Norway

  
Palani Damodharan  
Certification Manager