



NATALI SCOLARI
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Portuguese and English JUCISRS #0257
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Translation 838/115/2022 Book 05 Pages 299-302

I, Natali Scolari, appointed certified translator of Portuguese and English, registered under No.257 at the Rio Grande do Sul Trade Board (JUCISRS), do hereby certify that I was given a document to translate into English, which I have done in my official capacity, to wit and with the urgency required.

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[Logo] TÜVRheinland® Precisely Right.

Certificate of Compliance

Certificate n°: TÜV 19.0849 - Review 02

Applicant: INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA
Beco José Paris, 339 – Pavilhão 18 e 19 – Sarandi - 91140-310 – Porto Alegre – RS
CNPJ [Corporate Taxpayer Registration Number.]: 90.909.631/0001-10

Manufacturer: INSTRAMED INDÚSTRIA MÉDICO HOSPITALAR LTDA
Beco José Paris, 339 – Pavilhão 18 e 19 – Sarandi - 91140-310 – Porto Alegre – RS
CNPJ: 90.909.631/0001-10

Supplier/Legal Representative: Not applicable

Certification Scheme: Type 5 Certification, pursuant to INMETRO Ordinance #54, with Type Test, evaluation and approval of the manufacturer's Quality Management System, surveillance (follow-up) audits of the factory and testing of samples collected from the manufacturer, subject to evaluation and approval of the manufacturer's Risk Management.

Standards/ Regulation:

ABNT NBR IEC 60601-1:2010 +Amendment 1:2016
ABNT NBR IEC 60601-1-2:2010 ABNT NBR IEC 60601-1-6:2011
ABNT NBR IEC 60601-1-8:2010 + Amendment 1:2014
ABNT NBR IEC 60601-1-9:2010 + Amendment 1:2014*
ABNT NBR IEC 60601-2-4:2014, ABNT NBR IEC 60601-1-11:2012

* Only items 4.1, 4.5.2 and 4.5.3

According to the provisions of Ordinance #54, dated 01/02/2016- INMETRO [National Institute of Metrology, Standardization and Industrial Quality].

Pursuant to Resolution – RDC #27, dated June 21, 2011 - ANVISA [National Health Surveillance Agency].

Product: I.ON / I.ON PRO Automated External Defibrillator – Family Product
Certification

Issue and Validity: 05/07/2019. This review is valid from 04/07/2022 to 05/07/2024.

The validity of this Certificate of Compliance is subject to maintenance evaluations, according to the requirements set forth by the specific certification scheme. The updated status of this Certificate of Compliance may be verified on INMETRO's database for certified products and services.

[Signature]: Igor Moreno –Local Field Manager

[QR code] Digitally signed by TUV RHEINLAND DO BRASIL LTDA; 01950467000165

DN: c=BR, o=ICP-Brasil, st=SP, I=Sao Paulo, ou=Array, cn=TUV RHEINLAND DO BRASIL LTDA: 01950467000165

Reason: Digital Signature Location: Sao Paulo/SP/BR Date: 04.07.2022 21:02:50 +0000

This document is only valid when presented in full. The following pages contain further information and remarks.

Item	Brand	Model	Description	GTIN Barcode
1	INSTRAMED	I.ON	AED: internally energized Automated External Defibrillator, Battery Type: Rechargeable Li-Ion, 14.4VDC 4.0 A/h or non – rechargeable LiMnO ₂ , 18V 1400mAh, or non – rechargeable LiMnO ₂ , 18V 2800mAh. Charger: Input 100 – 220 V ~ 1 A, 50-60 Hz; Output: 16.8 VDC, 0.55 A, Defibrillation-proof type CF applied part, IP56, Non-continuous operation.	Non-existent
2	INSTRAMED	I.ON PRO	AED: internally energized device, Battery Type: Rechargeable Li-Ion, 14.4VDC 4.0 A/h or non – rechargeable LiMnO ₂ , 18V 2800mAh. Charger: Input: 100 – 220 V ~ 1 A, 50-60 Hz; Output: 16.8 VDC, 0.55 A, Defibrillation - proof type CF applied part, IP56, Non-continuous operation.	Non-existent

Laboratory and test report N°/ date:

IBEC - Brazilian Institute of Conformity Testing LTD.

Report #182739, dated 13/02/2019

Report #182739-1, dated 13/02/2019

Report #182739-2, dated 01/02/2019

Report #182739-3- Rev1.0, dated 18/06/2019

Report #192976, dated 17/04/2020

Report #192977, dated 17/01/2020

Report #192978, dated 31/01/2020

Pontificia Universidade Católica do Rio Grande do Sul [Pontifical Catholic University of Rio Grande do Sul]

LABELO - Specialized Laboratories in Electro-Electronics
Report #MED 0008/2019, dated 01/02/2019
Report #MED0013/2019, dated 21/03/2019
Report #MED0015/2019, dated 26/03/2019

Intertek Brazil Inspections LTD.
Report #0210-01-MED-19, dated 13/03/2019

NO RISK – Specialized Technical Services LTD.
Report #R182109, dated 10/12/2018
Report #R192144, dated 01/02/2019

INPE – National Institute for Space Research
LIT – Integration and Testing Lab
Report #NSTR04-R01 Version 01, dated 24/06/2019

Audit Report / Date: Audit performed on 19 and 20/11/2018 PO 0904-18.

This certificate is subject to: Proposal #27114103, accepted on 08/02/2019.

Specifications:

Evaluated Software Version: CPU1 - 1.22.00
CPU2 - 1.29.00
DISPLAY - 1.00.05 (PRO) and 1.00.01 (NOR)

Evaluated Version of User Manual and Product Design: User Manual: R2.0
Portuguese 2022-05-26.
RHProj: Version 1

List of accessories and parts tested with the product:

Code	Description
13940	01 Battery charger (optional).
5550	01 3-prong power cord (optional).
79047	01 Multifunctional adult size adhesive pad
80023	01 First Aid Kit.
13836 / 14015	01 Transport Bag (I.ON / I.ON PRO).
10985	01 USB A-B Cable.
25277	01 CD containing Instramed's manuals and softwares.
14002	01 Quick Reference Guide.
79048	01 Multifunctional child size adhesive pad (optional).
26005	01 3-lead ECG cable (optional).
11066	01 Chest compression device - CPR Maestro (optional).

Date/Nature of Reviews:

Review 00: 05/07/2019 – Initial Certification

Review 01: 09/02/2021 – Manual version alteration: VersionR1.5_Port
2019-05-17 to R1.10 Portuguese 2020-08-09.

Review 02:

Compliance to IEC 60601-1-11, with the addition of test reports and user manual's update.

TÜV 19.0849 – Review 02

Headquarters address: Rua Libero Badaró, 293, – 5º Andar, Conjunto G, Mezanino, Centro, CEP [Zip Code]: 01009-907, São Paulo - SP, CNPJ: 01.950.467/0005-99 – Tel.: 55 11 3514.5700 – www.tuv.com/br MS-0032141

[right-side margin]: To verify its authenticity please visit <https://tuv.3dds.digital/check/466463206039561219>

[left-side margin]: Pursuant to Provisional Measure #2.200-2, dated August 24, 2001, electronic statements produced via Digital Certification made available by ICP-Brasil are deemed true regarding the undersigned, pursuant to art. 219, of Act 10.406, of January 10, 2002 – Civil Code.

There was nothing else in the document presented to me. I, Natali Scolari, certify that this is a complete, true, and faithful translation of the said document.

Canoas, July 11th, 2022.

Fees: R\$ 395.00

MENEZES

Natali Scolari

Natali Scolari

Tradutora Juramentada - Inglês

Matrícula JUCERGS 0257



2º TABELONATO DE NOTAS PORTO ALEGRE

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Reconheço a **AUTENTICIDADE** da firma de: NATALI SCOLARI (0453.01.2100002.28050), indicada com a seta de uso deste Tabelionato.

EM TESTEMUNHO DA VERDADE
Porto Alegre, 11 de julho de 2022
Barbara Stempczynski Krause - Escrevente Autorizada

Rec.Firma: R\$ 6,00 - Hora: 16:33/44-34266

VÁLIDO SOMENTE SEM EMENDAS OU RASURAS

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