



Brasil

CERTIFICATE

No. INM1 102758 0003 Rev. 02**Supplier:****Mandala Brasil Importação e Distribuição
de Produto Médico Hospitalar Ltda**Av Horácio Raccanello, 5570, Salas 1201/1202, Zona 07
Paraná
87020-035 Maringá PR
BRAZIL

CNPJ 09.117.476/0001-81

Manufacturer:**Arcomed AG**

Steinackerstrasse 29, 8302 Kloten, SWITZERLAND

Product:**Volumetric Infusion Pump
Volumed µVP7000 series**

TÜV SÜD Brasil - OCP 0101 certifies that the referenced product is in accordance with the Inmetro Ordinance applicable for this product and Technical Standards applicable to the described scope and according to the technical data mentioned in this certificate. The certification mark sent to the supplier with this certificate shall be affixed on the product and should not be changed. The validity of this Certificate is linked to carrying out assessments maintenance and treatment of possible non conformities in accordance with TÜV SÜD Brasil - OCP 0101 orientation and foreseen in the specific Inmetro Ordinance. For verification of the updated compliance condition of this Certificate of Conformity, the data bank of certified products and services of INMETRO must be consulted. See www.tuvsud.com/ps-cert for details.

Certificate of Conformity valid only accompanied by the total pages indicated on the footer.

Test Report(s) / issue date:18-EL-0138.E01 -2018-12-19
60601-1-6_6000_7000_1119 - 2019-11-11
713258542 - 2023-03-01
713258542 Attachment #1-2 - 2023-01-23
713258542 Attachment #1-3 - 2023-01-13**Initial issue:**

2023-08-11

Revision issue:

2024-10-21

(Alice Maia)



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No. INM1 102758 0003 Rev. 02**Model(s):**

7T-XIP-01 – Volved μVP7000 – Chroma X, no door lock, PVC/PP, Upstream Occlusion Sensor, Internal Flow Stop, no WiFi
7T-XIP-01W – Volved μVP7000 – Chroma X, no door lock, PVC/PP, Upstream Occlusion Sensor, Internal Flow Stop, With WiFi
7T-XIS-01 – Volved μVP7000 – Chroma X, no door lock, Silicone, Upstream Occlusion Sensor, Internal Flow Stop, No WiFi
7T-XIS-01W – Volved μVP7000 – Chroma X, no door lock, Silicone, Upstream Occlusion Sensor, Internal Flow Stop, With WiFi
7T-XRP-03 – Volved μVP7000 – Chroma X, no door lock, PVC/PP, EasyClip, Robson Clamp, No WiFi
7T-XRP-03W – Volved μVP7000 – Chroma X, no door lock, PVC/PP, EasyClip, Robson clamp, with WiFi
7T-XRP-02 – Volved μVP7000 – Chroma X, no door lock, PVC/PP, Upstream occlusion sensor, Robson clamp, without WiFi
7T-XRP-02W – Volved μVP7000 – Chroma X, no door lock, PVC/PP, Upstream occlusion sensor, Robson clamp, with WiFi
7T-XRS-02 – Volved μVP7000 – Chroma X, no door lock, Silicone, Upstream occlusion sensor, Robson clamp, without WiFi
7T-XRS-02W – Volved μVP7000 – Chroma X, no door lock, Silicone, Upstream occlusion sensor, Robson clamp, with WiFi
7T-HYBA-W-BA – Volved μVP7000 – Chroma X, Hyperbaric with battery, PCA plug, no door lock, PVC/PP, upstream occlusion sensor, Robson clamp, no WiFi
7T-HYBA-W-BAW – Volved μVP7000 – Chroma X, Hyperbaric with battery, PCA plug, no door lock, PVC/PP, upstream occlusion sensor, Robson clamp, with WiFi
7T-HYBA-01 – Chroma X, Hyperbaric without battery, PCA plug, no door lock, PVC/PP, upstream occlusion sensor, Robson clamp, no WiFi
7T-HYBA-01W – Chroma X, Hyperbaric without battery, PCA plug, no door lock, PVC/PP, upstream occlusion sensor, Robson clamp, with WiFi

Trade name:**ARCOMED****Parâmetros/ Parameters:**

Tensão de Alimentação / Voltage (V):	110-230V
Potência / Power (VA)	19-27VA
Frequência/ Frequency (Hz):	50-60 Hz
Classe de Proteção/ Protection Class (IEC):	Class II / Classe II
Grau de Proteção/ Degree of Protection (IEC):	Applied part type CF / Parte aplicada tipo CF
Grau de proteção contra penetração nociva de água Degree of protection against harmful water penetration	IP32
Versão do Manual de Usuário avaliada em Português/ Version of Users manual evaluated in Portuguese:	GA7000C-4L-PT-0623
Versão do projeto do Produto avaliada/ Version of Product project evaluated	2.13
Versão do Software avaliada/ Version of Software evaluated:	6.XXXX

Accessories list see Annex on page 4

Name of testing laboratory(ies):
TÜV SÜD Product Service GmbH Munich
Eurofins Electrosuisse Product Testing AG, Lab Zürich
Factory inspection: 2024-07-19
Model of certification : 5

Date of acceptance of proposal: 2021-09-21

Certificate Validity: Undetermined as long as the requirements for its maintenance are met.



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In compliance to:

ABNT NBR IEC 60601-1:2010 + Emenda 1:2016
ABNT NBR IEC 60601-1-2:2017
ABNT NBR IEC 60601-1-6:2011 + Emenda 1:2020
ABNT NBR IEC 60601-1-8:2010 + Emenda 1:2014
ABNT NBR IEC 60601-1-9:2010 / AMD1:2014 (itens 4.1/4.5.2/4.5.3)
ABNT NBR IEC 60601-2-24:2015
IEC 62304:2006/AMD1:2015
Portaria/Ordinance INMETRO No.384 - 18/12/2020

Factory(ies):

Arcomed AG
Steinackerstrasse 29, 8302 Kloten, SWITZERLAND

Revision History:

2024-10-21	Factory inspection date updated. Update of models. Update of accessories list. Excluded the "Valid until from the first page and included the Certificate validity as undetermined on the second page.
2024-08-29	1st Maintenance.
2023-09-15	Correction of version of standard from IEC 62304:2006 to IEC 62304:2015.
2023-08-11	Initial issue. According to Ordinance 384/2020, this certificate has an indefinite validity, as long as the requirements for its maintenance are met.
The last revision replaces and cancels the previous ones Certificate with digital signature for electronic file. Authenticity can also be confirmed with the QR Code on page 1	



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ANNEX – Page 4

Accessories List
Mains cable
PCA-Button
Easy Clip Drop Detector
USB Arcomed IR Adapter for UniQueDOC and UniQueConcept
USB to serial converter for UniQueConcept
Nurse call cable for UniQueConcept
Mains cable for UniQueDOC and UniQueConcept
5411 – UniQueDOC– Pump docking station– 1 module
5412 – UniQueDOC – Pump docking station– 2 modules
5413 – UniQueDOC– Pump docking station– 3 modules
5414 – UniQueDOC– Pump docking station– 4 modules
5415 – UniQueDOC– Pump docking station– 5 modules
5416 – UniQueDOC– Pump docking station– 6 modules
5418 – UniQueDOC – Pump docking station– 8 modules
5320 – Unique MRI Shield – Protection MRI
5320-2 – Unique MRI Shield – Protection MRI – 2 modules
5320-4 – Unique MRI Shield – Protection MRI – 4 modules
5310-5411 – UniQueCONCEPT– 1 module
5310-5412 – UniQueCONCEPT– 2 modules
5310-5413 – UniQueCONCEPT– 3 modules
5310-5414 – UniQueCONCEPT– 4 modules
5310-5415 – UniQueCONCEPT– 5 modules
5310-5416 – UniQueCONCEPT– 6 modules
5310-5418 – UniQueCONCEPT– 8 modules

END OF ANNEX