ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD
Italia

CERTIFICATO

Nr. 50 100 5990/B - Rev.006

Si attesta che / This is to certify that

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

FAZZINI S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

STRADA STATALE PADANA SUPERIORE 317
IT - 20090 VIMODRONE (MI)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI CEI EN ISO 13485:2016

SISTEMI QUALITÀ – DISPOSITIVI MEDICALI
QUALITY SYSTEMS – MEDICAL DEVICES

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

VEDI ALLEGATO 1
SEE ANNEX 1

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Andrea Coscia
Direttore Divisione Business Assurance

Validità /Validity

Dal / From: 2018-10-01

Al / To: 2021-06-14

Data emissione / Printing Date
2018-10-01

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2006-07-02

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2018-06-14
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE 2018-06-14

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

T101-14/01

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Italia

ALLEGATO 1 AL CERTIFICATO NR 50 100 5990/B - Rev.006
ANNEX 1 TO CERTIFICATE NO 50 100 5990/B - Rev.006

IL CERTIFICATO NR 50 100 5990/B - Rev.006 È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE:: THE CERTIFICATE N 50 100 5990/B - Rev.006 IS VALID FOR THE FOLLOWING SCOPE:

Progettazione, gestione della fabbricazione, immissione in commercio e assistenza post vendita di dispositivi attivi chirurgici (aspiratori chirurgici), dispositivi non attivi per terapia intensiva (aspiratori chirurgici manuali), dispositivi attivi per la respirazione (aerosol) e loro accessori. Gestione della progettazione e della fabbricazione, immissione in commercio e assistenza post vendita di dispositivi non attivi con funzione di misura (sfigmomanometri, bilance), dispositivi non attivi per l'anestesia e l'emergenza e la cura intensiva (palloni, accessori per respirazione, anestesia ed aerosolterapia, immobilizzatori, laringoscopi endotracheali, set di pronto soccorso, barelle), dispositivi non attivi ortopedici e per la riabilitazione (ausili per disabili e riabilitazione), strumenti chirurgici non attivi, strumenti chirurgici attivi (elettrobisturi), dispositivi non attivi (dispositivi ospedalieri ed ambulatoriali per il supporto e la movimentazione del paziente e accessori, stetoscopi), dispositivi attivi non impiantabili e relativi accessori. Gestione della progettazione e della fabbricazione, immissione in commercio e assistenza post vendita di dispositivi attivi per monitoraggio (elettrocardiografi, pulsossimetri, monitor, bilance). Commercializzazione e assistenza post vendita di dispositivi non attivi per l'anestesia e l'emergenza e la cura intensiva (accessori per respirazione ed anestesia, accessori per medicazioni e per prelievi), dispositivi attivi per il posizionamento ed il trasporto del paziente (tavoli operatori), dispositivi attivi per la respirazione (accessori per respirazione), dispositivi attivi per la disinfezione e sterilizzazione (sterilizzatrici), dispositivi attivi per monitoraggio (termometri, misuratori di pressione), dispositivi per l'elettrochirurgia, la stimolazione o l'inibizione (stimolatori), dispositivi non attivi con funzione di misura (termometri)

Design, manufacturing management, trade and after sales service of active surgical devices (suction pumps), non-active devices for intensive care (manual suction pumps), active devices for breathing therapy (aerosol) and their accessories. Management of design and manufacture, trade and after sales service of non-active devices with a measuring function (blood pressure monitors, scales), non-active devices for anesthesia, emergency and intensive care (balloons, accessories for breathing, anesthesia and aerosol therapy, immobilizers, laryngoscopes endotracheal, first aid kit, stretchers), non-active devices for orthopedic and rehabilitation (aids for the disabled and rehabilitation), non-active surgical instruments, active surgical instruments (electrocautery), non-active devices (devices for hospitals and ambulatory for the support and movement of the patient and accessories, stethoscopes), non-active implantable devices and related accessories. Management of design and manufacture, marketing and after sales service of active devices for monitoring (electrocardiographs, pulse oximeters, monitors, scales). Trade and after sales service of non-active devices for anesthesia, emergency and intensive care (accessories for breathing and anesthesia, dressings and accessories for withdrawals), active devices for positioning and patient transport (operating tables) , active devices for respiration (breathing accessories), active devices for disinfection and sterilization (sterilizers), active devices for monitoring (thermometers, blood pressure monitors), devices for electrosurgery, stimulation or inhibition (stimulators), non active devices with a measuring function (thermometers)

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Andrea Coscia
Direttore Divisione Business Assurance

Validità /Validity
Dal / From: 2018-10-01
Al / To: 2021-06-14

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2018-10-01

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"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
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T101:14/01

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Product Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex VI
(Devices in class IIa or IIb)

No. G3 16 06 44963 026

Manufacturer:

Fazzini s.r.l.
SS Padana Sup. 317
20090 Vimodrone (MI)
ITALY

Facility(ies):

Fazzini s.r.l.
SS Padana Sup. 317, 20090 Vimodrone (MI), ITALY

Product Category(ies):

Suction Pumps

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for final inspection and test of the respective devices / device categories in accordance with MDD Annex VI. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report no.: ITA274457

Valid from: 2016-10-22
Valid until: 2021-10-21

04052758905970

Date, 2016-09-30

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

"Astar ABR"
Aleksander Jedrzejowski,
Robert Dziendziel Spolka Jawna
ul. Swit 33
43-382 Bielsko-Biala
Poland

has established and applies a quality management system for medical devices for the following scope:

(see attachments for scope included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-01-12
Certificate Registration No.:	SX 60125636 0001
An audit was performed. Report No.:	26300254 005
This Certificate is valid until:	2020-12-11

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-01-12

Maciej Sciera

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60125636 0001
Report No.: 26300254 005

Organization:
"Astar ABR"
Aleksander Jedrzejowski,
Robert Dziendziel Spolka Jawna
ul. Swit 33
43-382 Bielsko-Biala
Poland

Scope:

Design and development, manufacture, distribution, installation and servicing of active medical devices for electrotherapy, laser therapy, light therapy, ultrasound therapy, magnetic field therapy, vacuum therapy and shock wave physical therapy

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2018-01-12

Maciej Sciera

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate
Registration No.: HD 60097823 0001
Report No.: 26300254 001

Manufacturer:
"Astar ABR"
Aleksander Jedrzejowski,
Robert Dziendziel Spolka Jawna
ul. Swit 33
43-382 Bielsko-Biala
Poland

Products included:

- Electrotherapy devices
- Laser therapy devices
- Light therapy devices
- Magnetic field therapy devices
- Ultrasound therapy devices
- Ultrasound therapy combined with electrotherapy devices
- Vacuum therapy devices
- Shock wave physical therapy devices

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

D. Swiatko

Date: 2014-12-12

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

has established and applies a quality management system for medical devices for the following scope:

Design and development, manufacturing, distribution and servicing of ventilators and ventilator systems (see attachment for additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-03-06
Certificate Registration No.:	SX 60136805 0001
An audit was performed. Report No.:	21213508 012
This Certificate is valid until:	2020-07-08

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date 2019-03-06

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.0

Attachment to Certificate
Registration No.: SX 60136805 0001
Report No.: 21213508 012

Organization:
Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Scope:

Additional site:

Hamilton Medical AG
Parc Industrial Vial 10
7013 Domat/Ems
Switzerland

Activities: Manufacturing and Service

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2019-03-06

Dipl.-Ing. I. Munkler

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60137935 0001

Report No.: 21213508 015

Manufacturer:
Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Products: Ventilators and ventilator systems

(see attachment for additional site included)

Replaces Approval, Registration No.: HD 60136804 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-07-09

Date: 2019-04-02

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate
Registration No.: HD 60137935 0001
Report No.: 21213508 015

Manufacturer:
Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Additional site:

Hamilton Medical AG
Parc Industrial Vial 10
7013 Domat/Ems
Switzerland

Date: 2019-07-09

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. I. Munkler