Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)

No. G2M 063105 0048 Rev. 00

Manufacturer:

CA-MI S.R.L.
Via Ugo La Malfa, 13
Frazione Pilastro
43013 Langhirano (PR)
ITALY

Facility(ies):

CA-MI S.R.L.
Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR),
ITALY

Product Category(ies):

Various canister, suction unit, aneroid sphygmomanometer and mercury free clinical thermometer

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: ITA1319360M

Valid from: 2019-09-26
Valid until: 2024-05-26

Date, 2019-09-26

Stefan Preiß
Head of Certification/Notified Body

REPUBLICA MOLDOVA, CHIŞINĂU, SOCIETATEA PE ACŢIUNI S.A. M.INTER FARMA IDNO 1003600005263 1994

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

Digitally signed by Palii Nina
Date: 2020.03.04 14:49:27 EET
Reason: MoldSign Signature
Location: Moldova

TÜV®

A4 / 07.17

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 063105 0045 Rev. 01

Holder of Certificate: **CA-MI S.R.L.**
Via Ugo La Malfa, 13
Frazione Pilastro
43013 Langhirano (PR)
ITALY

Certification Mark:

Scope of Certificate: **Design and development, production, sale and after-sales technical assistance of medical equipments for surgery (electrical and manual suction pumps), electric breast pumps, medical devices for breathing (aerosol therapy equipments and thermal water inhaler), medical devices for stimulation (tens) and related accessories. Placing on the market under its own name of devices for monitoring of vital physiological parameters (pulse oximeters, thermometers, blood pressure monitors, sphygmomanometer and stethoscopes), incentive spirometers, devices for phlebology (graduated compression medical stockings) and anti-decubitus mattress.**
Distribution of active and non-active non implantable medical devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: ITA1254731

Valid from: 2019-08-01
Valid until: 2022-07-31

Date, 2019-07-30

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 063105 0045 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

CA-MI S.R.L.
Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR), ITALY

CA-MI S.r.l.
Via Strada per Parma 34, Frazione Pilastro, 43013 Langhirano PR, ITALY

Facility(ies) Scope:

CA-MI S.R.L.
Via Ugo La Malfa, 13, Frazione Pilastro, 43013 Langhirano (PR), ITALIA
Design and development, production, sale and after-sales technical assistance of medical equipments for surgery (electrical and manual suction pumps), electric breast pumps, medical devices for breathing (aerosol therapy equipments and thermal water inhaler), medical devices for stimulation (tens) and related accessories. Placing on the market under its own name of devices for monitoring of vital physiological parameters (pulse oximeters, thermometers, blood pressure monitors, sphygmomanometer and stethoscopes), incentive spirometers, devices for phlebology (graduated compression medical stockings) and anti-decubitus mattress.
Distribution of active and non-active non implantable medical devices.

CA-MI S.R.L.
Via Strada per Parma, 34, Frazione Pilastro, 43013 Langhirano (PR) Italy
Warehouse of active and non-active non implantable medical devices and components used in production

REPUBLICA MOLDOVA, CHIȘINĂU, SOCIETATEA PE ACȚIUNI
IDNO 1003600005263
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TÜV®

Dr. Mach
medical lighting + technology

CE EC - Declaration of Conformity

In accordance with Annex I and VII of the EC Directive 93/42/EEC concerning medical devices, last amended by Directive 2007/47/EC of 5 September 2007

Manufacturer: Dr. Mach GmbH & Co. KG
Flossmannstraße 28
D-85560 Ebersberg (Germany)

the undersigned herewith confirms under his own responsibility that the products listed below

Type designation:
Mach 130, Mach 130F, Uniflex
Mach LED 110
Mach LED 115, Mach LED 115C
Mach LED 120, Mach LED 120F
Mach LED 130, Mach LED 130F, Mach LED 130 Plus
Mach LED 130 Dental, Mach LED 130 Dental P
Mach LED 150, Mach LED 150F, Mach LED 150FP
Mach LED 300 DF
Mach LED 2MC, Mach LED 2SC, Mach LED 2SC Hybrid
Mach LED 2 Smart
Mach LED 3MC, Mach LED 3SC
Mach LED 3 Smart
Mach LED 5MC, Mach LED 5SC
Mach LED 5 Smart

Instrument and equipment racks with double sockets and PA sockets
VDU support
Doctor's instrument table, hand operating table

Video system HDMV
Video system HDMV-F

complies with the basic requirements and provisions of the following directive:

Directive **93/42**/EEC, Annex I of the Council of 14 June 1993 concerning medical devices

Standards:
EN 60601-1 : 2013 (IEC 60601-1)
EN 60601-1 : 2006 (IEC 60601-1)
EN 60601-2-41 : 2010 (IEC 60601-2-41)
EN 60601-2-41 : 2016-02 (IEC 60601-2-41)
EN 60601-1-2 :2007
EN 60601-1-2 :2015

Class: The examination and/or operating lamps and their accessories are Class I active medical products according to Annex IX of the Directive

Labeling is by means of the mark: CE

This certificate is valid until: December 20th 2023

ppa.

Ebersberg
Town

December 20th 2018
Date

Dr. Peter Kohrs
Technical Manager

59593002 / 20.12.2018

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60140658 0001
Report No.: 21248610 004

Organization:
Dr. Mach GmbH & Co. KG
Medizintechnik
Flossmannstr. 28
85560 Ebersberg
Deutschland

Scope:

Design and development, production, distribution, installation and service of operating lamps, video systems and examination lamps.
Contract manufacture for mechanical components.

Site included:

Dr. Mach GmbH & Co. KG
Medizintechnik
Anzinger Straße 12
85560 Ebersberg, Germany

Activity: Production

Certification Body

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

Date: 2019-07-08

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Dr. Mach GmbH & Co. KG
Medizintechnik
Flossmannstr. 28
85560 Ebersberg
Deutschland

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

scope: see attachment

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:	2019-07-08
Certificate Registration No.:	SX 60140658 0001
An audit was performed. Report No.:	21248610 004
This Certificate is valid until:	2022-06-19

Certification Body

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

Date 2019-07-08

Roland Gruber

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

TÜV NORD

CERTIFICATE

Management system as per
PN-EN ISO 13485:2016-04
Medical devices - Quality management systems - Requirements for regulatory purposes

In accordance with TÜV NORD Polska Sp. z o.o. procedures, it is hereby certified that

ULTRA-VIOL Sp. j.
Pietras, Purgał, Wójcik
ul. Stępowizna 34, PL / 95-100 Zgierz

ULTRAVIOL

applies a management system in line with the above standard for the following scope

Design and development, manufacturing, distribution, installation and service of phototherapy lamps, digital image viewing stations, X-ray film viewers, germicidal lamps and devices, software for own medical devices.

Regardless of the fact that TÜV NORD Polska Sp. z o.o. is a notified body No. 2274 in the area of medical devices, this Certificate is not a Certificate of Conformity within the meaning of Directive 93/42/EEC and is not a basis for CE marking.

Certificate Registration No. **AC090 MD/1303/828/2015**
Audit Report No. PL828/2018

Valid from **26-10-2018**
Valid until **21-10-2021**
Initial certification: 22-10-2012

Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

Katowice, 26-10-2018

This certification was conducted in accordance with the TÜV NORD Polska Sp. z o.o. auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD Polska Sp. z o.o. ul. Mickiewicza 29 40-085 Katowice www.tuv-nord.pl

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 090
QMS

REPUBLICA MOLDOVA, CHIȘINĂU, SOCIETATEA PE ACȚIUNI S.A. M·INTER·FARMA IDNO 1003600005263 1994

ULTRA VIOL

DECLARATION OF CONFORMITY

CE

The undersigned company:

ULTRA – VIOL Sp. j. Pietras Purgał Wójcik
ul. Stępowizna 34; 95-100 Zgierz,

declares that the non-medical devices **germicidal flow lamps, type:**

NBVE 60;	**NBVE 60/30;**
NBVE 110;	**NBVE 110/55;**

in realization: **N** – wall mounted, **S** – ceilling mounted, **P** – on mobile stand
(-) – without work time counter;
L – with work time counter without display;
LW – with work time counter with display;
LW ST – with work time counter with display and switch-key;
RC – with remote control; **MD** – with motion detector

marked with **CE** mark, are electrical devices that conform the essential requirements stated in the following EC – Directives:

- **2014/35/EC (LVD),**
- **2014/30/EC (EMC),**
- **93/42/EEC and 2007/47/EC (some requirements).**

The devices conforms the harmonized European standards:

• **EN 60601-1**	**Medical electrical equipment** -- Part 1: General requirements for basic safety and essential performance
• **EN 60601-1-2**	**Medical electrical equipment** – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
• **EN 60598-1**	Luminaires – Part 1: General requirements and tests
• **EN 61547**	Equipment for general lighting purposes - EMC immunity requirements
• **EN 60529**	Degrees of protection provided by enclosures (IP code)

We declare with full responsibility that the products meet the requirements of the **RoHS directive 2011/65/EU** (including all its changes and amendments). Conformity assessment was carried out according to standard **EN 50581**.

Quality Management System of ULTRA-VIOL certified by TUV Nord meets requirements of:

- **EN ISO 13485:2016 - Medical devices** – Quality management systems – Requirements for regulatory purposes

04 – year of marking with CE mark

on behalf of ULTRA-VIOL Sp. j.

Wiesław Pietras
GENERAL MANAGER

REPUBLICA MOLDOVA, CHIȘINĂU, SOCIETATEA PE ACȚIUNI
IDNO 1003600005263
S.A. M·INTER FARMA
1994

Zgierz, 5th November 2018

Kenmak

CE

EC DECLARATION OF CONFIRMITY
AT UYGUNLUK BEYANI

We, KENMAK Hastane Malzemeleri ve Elektrostatik Boya San. Tic. ve A.Ş., hereby declare that the below mentioned products have been designed and manufactured according to Directives of European Commission and realated other standarts.

RULE 1 CLASS 1- 93/42/EEC ANNEX-7
TS EN ISO 13485
TS EN 60601
TS EN ISO 14971
TS 9215

Biz, KENMAK Hastane Malzemeleri Ve Elektrostatik Boya San. Tic. ve A.Ş., ekte verilen ürünleri Avrupa Komisyonu direktifi ve ilgili diğer standartlara uygun olarak tasarladığımızı ve ürettiğimizi beyan ederiz.

KURAL 1 SINIF 1- 93/42/EEC EK-7
TS EN ISO 13485
TS EN 60601
TS EN ISO 14971
TS 9215

REPUBLICA MOLDOVA, CHIŞINĂU, SOCIETATEA PE ACȚIUNI
IDNO 1003600005263
S.A. M·INTER FARMA
1994

Date of Beginning / Başlangıç Tarihi : 16.01.2018
Expiry Date / Bitiş Tarihi : 16.01.2023
Name & Signature (İsim/İmza) : Kenan KILIÇ
Board Chairman /Yönetim Kurulu Başkanı

KENMAK HASTANE MALZEMELERİ VE ELEKTROSATİK BOYA SAN. VE TİC. A.Ş.
SARNIÇ YOLU ÜZERİ NO: 23 GAZİEMİR – İZMİR / TURKEY
Tel: +90 (232) 274 1717 [Pbx] Fax: +90 (232) 274 6777 www.kenmak.com.tr ~ kenmak@kenmak.com.tr

Technical Universal Verification

CERTIFICATE

This Certificate has been awarded to:

KENMAK HASTANE MALZEMELERİ VE ELEKTROSTATİK BOYA SAN. TİC. A.Ş.

DOKUZ EYLÜL MAHALLESİ SARNIÇ YOLU ÜZERİ NO:23 GAZİEMİR

İZMİR - TURKEY

In Recognition of the Organisation's Management System which complies with:

ISO 13485 : 2016

For the Scope of Activities described below:

DESIGN, PRODUCTION, SALES AND TECHNICAL SERVICE OF HOSPITAL EQUIPMENTS

Certificate No : 4111

Date of Audit : 20.10.2018

Date of Registration : 12.11.2018

Reissue Date : 04.10.2019

Expiry Date : 11.11.2020

Technical Universal Verification

This document is valid for 3 years provided that the management system is well maintained and surveillance audits are performed regularly.
After performing the surveillance audits certificate will be reissued. The current status of this certificate can be viewed via www.techcert.com.tr web site.
This certificate is a property of Technical Universal Verification Certification and Training Services Co., Ltd.
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Technical Universal Verification
Belgelendirme ve Eğitim Hizmetleri Ltd. Şti.
Macun Mahallesi Batı Bulvarı ATB İş Merkezi A Blok
No: 1/3 Yenimahalle - ANKARA / TURKEY
Tel.: 00 90 312 231 82 02
• web: www.techcert.com.tr
• e-mail: info@techcert.com.tr

UNITED ACCREDITATION FOUNDATION UAF

CB - MS - 0602