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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

TÜVRheinland®

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

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

Ebersberg
Town

December 20th 2018
Date

pp. Dr. Peter Kohrs
Technical Manager

59593002 / 20.12.2018

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

FAMED
Żywiec

FAMED Żywiec Sp. z o.o.
ul. Fabryczna 1, PL / 34-300 Żywiec

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

Design, development, production, distribution and service of ICU beds, rehabilitation beds and hospital beds, delivery beds, baby cots, operating and treatment tables, gynecological and treatment chairs, patient transport trolleys, luminaires and relevant accessories.

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/1202/139/2016**
Audit Report No. PL139/2019

Valid from **07-10-2019**
Valid until **13-09-2022**
Initial certification: 23-09-2016

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

Katowice, 07-10-2019

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.

AC 090
QMS

DEKLARACJA ZGODNOŚCI
DECLARATION OF CONFORMITY

No. / *Nr 4/2020*

Wytwórca / *Manufacturer:*

FAMED Żywiec

FAMED ŻYWIEC
Spółka z ograniczoną odpowiedzialnością

34-300 Żywiec, Fabryczna 1, Poland
tel.: +48 33 866 62 00, fax: +48 33 475 58 90
e-mail: famed@famed.com.pl

Nazwa wyrobu / *Product name:* **Stół operacyjny** ***Operating table***

Typ / *Type:* **SU-03, SU-04, SU-05, SU-06, SU-07**

Nazwy dodatkowe/ *Additional names:* ***OPTIMA, FLARE***

GMDN: **33152**

Wyrób oznaczony znakiem CE jest urządzeniem medycznym wg Dyrektywy Rady 93/42/EWG dotyczącej wyrobów medycznych i spełnia wymagania zasadnicze określone w załączniku I tej dyrektywy. Jest to wyrób klasy I wg reguły 12, klasyfikacja wyrobu została przeprowadzona zgodnie z załącznikiem IX tej dyrektywy. Ocena zgodności została przeprowadzona zgodnie z załącznikiem VII tej dyrektywy.
Równocześnie wyrób spełnia wymagania wynikające z krajowych przepisów prawnych. Jest wyrobem medycznym zgodnie z Ustawą z dnia 20 maja 2010 r. o wyrobach medycznych (t.j. Dz.U. 2017.211) i spełnia wymagania zasadnicze oraz procedury oceny zgodności określone w Rozporządzeniu Ministra Zdrowia z dnia 17 lutego 2016 r. (Dz.U. 2016.0.211). Klasyfikacja wyrobu została przeprowadzona zgodnie z Rozporządzeniem Ministra Zdrowia z dnia 5 listopada 2010 r. (Dz.U. 2010.215.1416).

The product marked with CE sign is a medical device according to Medical Device Directive 93/42/EEC and meets essential requirements defined in Annex I of this directive. It's product in Class I according to Rule 12, classification was carry out in accordance with Annex IX of this directive. The conformity evaluation was carried out in accordance with Annex VII of this directive.
At the same time product meets requirements of coming from national legislation. It is a medical device in accordance with the Act of 20 May 2010 on medical devices (t.j. Dz.U. 2017.211) and meets the essential requirements and conformity assessment procedures set out in the Regulation of the Health Minister of 17 February 2016 (DZ.U. 2016.0.211). Classification of the product was carried out according to the Regulation of the Health Minister on 5 November 2010 (Dz.U. 2010.215.1416).

Seryjny nr / Serial nr:

Żywiec, 19.03.2020

CE

FAMED ŻYWIEC Sp. z o.o.
34-300 Żywiec, ul. Fabryczna 1
Reg. 146369568 NIP 5272685925
tel. 33 86 66 200

pieczęć firmowa
(company stamp)

Imię i nazwisko:
(First name and surname)
Stanowisko:
(Position)

Opracował (*Elaborated by):*
Dariusz Talik
Główny Konstruktor
Development Manager

Główny Konstruktor
mgr inż. Dariusz Talik

Zatwierdził (*Approved by):*
Marek Suczyk
Wiceprezes, Dyrektor ds marketingu i sprzedaży
Vice President, Sales & Marketing Director

Vice President, Sales & Marketing
Marek Suczyk

podpisy i pieczęcie (*signatures and stamps*)