

bsi.



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

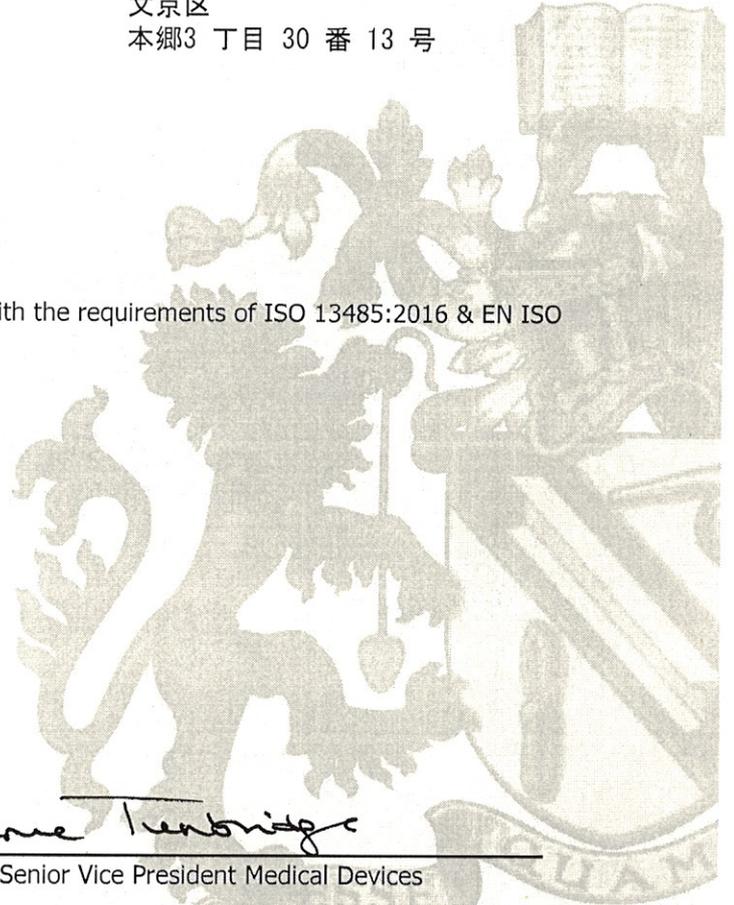
This is to certify that: MIZUHO Corporation
3-30-13 Hongo,
Bunkyo-ku,
Tokyo
113-0033
Japan

ミズホ株式会社
〒113-0033
東京都
文京区
本郷3 丁目 30 番 13 号

Holds Certificate No: MD 766899

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Please see scope page.



For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-09-07

Latest Revision Date: 2023-08-21

Effective Date: 2023-08-21

Expiry Date: 2026-08-20

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory or telephone 045-414-3022

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.



CE Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
MIZUHO Corporation	3-30-13 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan	-

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	email
Emergo Europe B.V.	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL - AR - 000000116	EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	Product Code / Catalog Number	Basic UDI-DI
Operating Table MOT-5602BW	Attachment 1	GMN 49463290218002UF
Intended Purpose		Photo
It is a mobile operating table and can be adapted to most of the surgical positioning required for various surgeries.		-

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class I Rule 13	N/A

The MIZUHO Corporation declares that the above-mentioned products meet the provision of the following EU legislation:

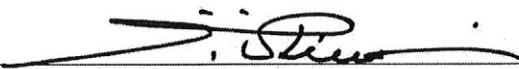
- MDR (EU) 2017/745
- Directive 2011/65/EU, (EU) 2015/863

COMPANY REPRESENTATIVE: Toshimi SHIUN

TITLE: Executive Officer & Department Head
Quality Assurance & Regulatory Affairs
Department

PLACE: Tokyo, Japan

SIGNATURE:



DATE: 2021-07-07



Attachment 1**[Operating Table MOT-5602BW]**

Product Code	Trade Name	Product Description
18-450-10	Operating Table MOT-5602BW	MOT-5602BW
18-450-20	Operating Table MOT-5602BW	MOT-5602BW (ASIA)
18-450-30	Operating Table MOT-5602BW	MOT-5602BW (EU)
18-450-70	Operating Table MOT-5602BW	MOT-5602BW (US)