SHIMADZU

CE 0197

ZCCM-0103AM

EC Declaration of conformity

This Declaration of Conformity is related to each product release.

Manufacturer	:	**SHIMADZU CORPORATION** **Medical Systems Division**
Address	:	**1, NISHINOKYO-KUWABARACHO,** **NAKAGYO-KU, KYOTO, 604-8511, JAPAN**
Authorized Representative in EU	:	**FUJIFILM Europe GmbH**
Address	:	**Balcke-Duerr-Allee 6, 40882 Ratingen, Germany**

declares, in sole responsibility, that the following product

Product Name	:	**Mobile X-ray System**
Model Name	:	**Mobile X-ray System FDR Go**
*The same model is sold under the following marketing names	:	**FDR Go, FDR Go PLUS**

Parts Number	:	**566-20000-18**
MDD Classification	:	**IIb (Rule10)**
GMDN Code	:	**37647**
UMDNS Code	:	**13272**

are compliant with **Annex I** of the Following Directives and Standards.

Directive:

Medical Device Directive	:	93/42/EEC
RoHS Directive	:	2011/65/EU (as amended by Directive (EU) 2015/863)

Standards:

MDD :	EN 60601-1:2006+A11+A1+A12,	EN 60601-1-2:2015,	EN 60601-1-3:2008+A1+A11,
	EN 60601-1-6:2010+A1,	EN 60601-2-54:2009+A1,	EN 60627:2001,
	EN 62366:2008+A1,	EN 62220-1:2004,	EN ISO 10993-1:2009,
	EN ISO 14971:2012,	EN ISO 1041:2008,	EN ISO 15223-1:2016,
	EN 62304:2006+AC2008		
RoHS :	EN IEC 63000:2018		

Conformity Assessment Procedure: **Annex II excluding Section 4 for 93/42/EEC**
The company's Quality System is satisfied with **Annex II excluding Section 4 for 93/42/EEC**, which is certified by **TUV Rheinland LGA Products GmbH**; Tillystrasse 2, 90431 Nuremberg, Germany **(Notified under No. 0197)** as **Registration No.: HD 60147504 0001**

The company named above will keep on file for review the following technical documentation:
*operating and maintenance instructions
*technical drawings
*description of measures designed to measure conformity
*other technical documentation, e.g. quality assurance measures for design and production

Note: This declaration becomes invalid if technical or operational modifications are introduced without the manufacturer's consent.

Note: The Parts Number is identification for the specific model or type of product in our company, the products of same parts number described in DoC will be produced in the same specification, and it will be complied with the requirements for CE-marking.

Refer to Technical file for (MDD) ZCCE-0103AG / (RoHS) ZCCR-0005Y

This declaration as RoHS is valid for the products manufactured on or after Serial Number MQ00012B4074.

16, Nov. 2022 (issued date) K. Kataoka (signature)

Kyoto, Japan (place) Koichi Kataoka (full name)

General Manager, Quality Assurance Department,
Medical Systems Division,
Shimadzu Corporation

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Annex of Declaration of Conformity ZCCM-0103AM

Product Name : **Mobile X-ray System**
Model Name : **Mobile X-ray System FDR Go**

Please refer the following additional information EC Declaration of Conformity. This information is to be maintain with corresponding EC Declaration of Conformity.

This Model is consisted of the following product.

Product Group	**Model Name**	**P/N**
X-ray tube housing assembly	**0.7/1.3U163C-36**	**582-24780-62**