

DECLARATION OF CONFORMITY

SIMAD s.r.l.

Società Unipersonale
Direzione e coordinamento
di Sago Medica s.r.l.

Via Benedetto Zallone 25
40066 Pieve di Cento, Bologna
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C.F./P.I./Reg.Imp.di Bologna 01854280367
VAT Number: IT 01854280367
REA di Bologna 433497
Iscr. RAEE IT09110000006357
Reg. PILE IT17020P00004368
Cap. Soc. € 76.500,00 I.V.



CONCEIVED
DESIGNED and
MANUFACTURED
IN ITALY

CI-SIMAD-03-2017

MANUFACTURER	SIMAD SRL
ADDRESS	VIA BENEDETTO ZALLONE 25, 40066, PIEVE DI CENTO (BO), ITALIA
WEBSITE	WWW.SIMAD.NET
TEL.	+390516860811
MEDICAL DEVICE'S NAME	MOONRAY
TRADEMARK	SIMAD
MODEL AVAILABLE	• 500 • PRECISIO • DUAL • COMPACT
SRN EUDAMED	IT-MF-000027245
INTENDED PURPOSE	Moonray is mobile fluoroscopy medical device intended for provide fluoroscopic and digital image of adult and pediatric population, during diagnostic, interventional and surgery procedure.
RISK CLASS	IIB (<i>according to annex VIII regulation 10 of Reg. UE 2017/745</i>)
BASIC UDI-DI	805714374MOONRAYWF
NOTIFIED BODY	IMQ S.p.A no. 0051
No. CERTIFICATE	110/MDR
CONFORMITY ASSESSMENT PROCEDURE	According to Annex IX chapter I and III of Regulation UE 2017/745

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Model: COMPACT	Model: DUAL	Model: PRECISIO	Model: 500
Catalogue number	Catalogue number	Catalogue number	Catalogue number
EMC I9L1 G	EMD I9L1 G	EMP I9L1 G	EMS I9L1 G
EMC I9L1 P	EMD I9L1 P	EMP I9L1 P	EMS I9L1 P
EMC I9L1 V	EMD I9L1 V	EMP I9L1 V	EMS I9L1 V
EMC I9M1 G	EMD I9M1 G	EMP I9M1 G	EMS I9M1 G
EMC I9M1 P	EMD I9M1 P	EMP I9M1 P	EMS I9M1 P
EMC I9M1 V	EMD I9M1 V	EMP I9M1 V	EMS I9M1 V
EMC I9H1 G	EMD I9H1 G	EMP I9H1 G	EMS I9H1 G
EMC I9H1 P	EMD I9H1 P	EMP I9H1 P	EMS I9H1 P
EMC I9H1 V	EMD I9H1 V	EMP I9H1 V	EMS I9H1 V
EMC F2L1 G	EMD F2L1 G	EMP F2L1 G	EMS F2L1 G
EMC F2L1 P	EMD F2L1 P	EMP F2L1 P	EMS F2L1 P
EMC F2L1 V	EMD F2L1 V	EMP F2L1 V	EMS F2L1 V
EMC F2M1 G	EMD F2M1 G	EMP F2M1 G	EMS F2M1 G
EMC F2M1 P	EMD F2M1 P	EMP F2M1 P	EMS F2M1 P
EMC F2M1 V	EMD F2M1 V	EMP F2M1 V	EMS F2M1 V
EMC F2H1 G	EMD F2H1 G	EMP F2H1 G	EMS F2H1 G
EMC F2H1 P	EMD F2H1 P	EMP F2H1 P	EMS F2H1 P
EMC F2H1 V	EMD F2H1 V	EMP F2H1 V	EMS F2H1 V
EMC F3L1 G	EMD F3L1 G	EMP F3L1 G	EMS F3L1 G
EMC F3L1 P	EMD F3L1 P	EMP F3L1 P	EMS F3L1 P
EMC F3L1 V	EMD F3L1 V	EMP F3L1 V	EMS F3L1 V
EMC F3M1 G	EMD F3M1 G	EMP F3M1 G	EMS F3M1 G
EMC F3M1 P	EMD F3M1 P	EMP F3M1 P	EMS F3M1 P
EMC F3M1 V	EMD F3M1 V	EMP F3M1 V	EMS F3M1 V
EMC F3H1 G	EMD F3H1 G	EMP F3H1 G	EMS F3H1 G
EMC F3H1 P	EMD F3H1 P	EMP F3H1 P	EMS F3H1 P
EMC F3H1 V	EMD F3H1 V	EMP F3H1 V	EMS F3H1 V

This declaration of conformity is issued under the sole responsibility of the manufacturer, SIMAD srl with legal basis on Via Benedetto Zallone 25, 40066, Pieve di Cento (Bo), Italia, P.Iva: 01854280367, REA di Bologna: 433497,

DECLARE

That the medical devices here indicate are compliant with:

- UE Regulation 2017/745 (MDR);
- Directive 2006/42/CE;
- Directive 2011/65/UE;
- Directive 2012/19/UE;
- UE Regulation 2016/679;
- Euratom Directive 2013/59;
- ISO 13485:2016;
- ISO 14971:2019;
- ISO 24971:2020;
- ISO 15223-1:2021;
- ISO 9001:2015;
- EN 60601-1:2006/ A11:2011/A1:2013/A12:2014/A2:2021;
- IEC 60601-1-2:2014+AMD1:2020;
- IEC 60601-1-3:2008 + AMD1:2013+AMD2:2021;
- IEC 60601-2-54:2009+ AMD1:2015+AMD2:2018;
- IEC 60601-1-6:2010+ AMD1:2013 +AMD2:2020;
- IEC 60601-2-28:2017;
- IEC 60601-2-43:2010+AMD1:2017+AMD2:2019;
- IEC 62304:2006+AMD1:2015;
- IEC 62366-1:2015+AMD1:2020;
- IEC 60825-1:2014.

Pieve di Cento, June 23, 2023

Luogo, data
Place, date


SIMAD S.R.L.
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Cod. Fisc. e P.IVA 01854280367

Franco Fallavena
Amministratore Delegato
Managing Director

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