SCHILLER MEDICAL
4, rue Louis Pasteur
67160 Wissembourg – France

Téléphone +33 (0) 3 88 63 36 00

Télécopie +33 (0) 3 88 94 12 82

Internet : http://www.schiller-medical.com
Email : info@schiller.fr

SCHILLER
MEDICAL

DECLARATION OF CONFORMITY WITH DIRECTIVES 93/42/CEE AND 2014/53/UE

File N° : CE ARE 0131

PRODUCT
Name : MAGLIFE RT-1
Function : Monitoring systems

Commercial reference or article code:

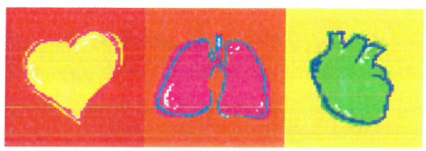
1-131-9901	MAGLIFE RT-1 ESN
1-131-9902	MAGLIFE RT-1 ESNPC
1-131-9903	MAGLIFE RT-1 ESNPCAO
1-131-9904	MAGLIFE RT-1 ESNPCAOT
1-131-9905	MAGLIFE RT-1 ESNPCAOR
1-131-9906	MAGLIFE RT-1 ESNPCAORT
1-131-9907	MAGLIFE RT-1 SNC

Abbreviation:
E : ECG
S : SpO2
N : NIBP
P : PI
C : CO2
A : Anesthetic agents
O : O2
T : Temperature
R : Respiration

Classification : **II b** in accordance with rule 10 below of classification of medical device of Directive 93/42/CEE
"Active device intended for diagnosis are in class IIa:

- If they are intended to supply energy which will be absorbed by the human body, except for device used to illuminate the patient's body, in the visible spectrum.
- If they are intended to image in vivo distribution of radiopharmaceuticals;
- If they are intended to allow direct diagnosis or monitoring of vital physiological processes,

unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CN in which case in Cass IIb."



SAS au capital de 5 180 800 € - Siret 310 967 294 000 52 – NAF 2660 Z – N° identification TVA : FR 29 310 967 294

SCHILLER MEDICAL
4, rue Louis Pasteur
67160 Wissembourg – France

Téléphone +33 (0) 3 88 63 36 00

Télécopie +33 (0) 3 88 94 12 82

Internet : http://www.schiller-medical.com
Email : info@schiller.fr

Number : **Composition of the number 13199sxxxxxx**
13199 : MAGLIFE RT-1
s : Device serial number
xxxxxx : Unit number

MANUFACTURER

Address of the manufacturer: SCHILLER MEDICAL
4, rue Louis Pasteur
67160 Wissembourg -France

STANDARDS APPLIED

IEC 60601-1	IEC 60601-1-2	IEC 60601-1-6	IEC 60601-1-8
IEC 60601-2-27	IEC 80601-2-30	IEC 60601-2-34	IEC 60601-2-49
IEC 80601-2-55	IEC 80601-2-56	IEC 80601-2-61	IEC 62304
IEC 62366			

NOTIFIED BODY

Number: 0459
Name : GMED
Address: 1, rue Gaston Boissier 75724 PARIS CEDEX 15-France

PROOF OF CONFORMITY WITH MAIN REQUIREMENTS WITH DIRECTIVES USED

Directive 93/42/CEE
Annex II : CE certificate n° 23223 rev.9 issued by GMED, on April 21, 2021.

Directive 2014/53/UE
Standards applied :
- Safety and health (ART 3.1.a) : serial IEC 60601
- CEM (ART 3 .1b) : IEC 60601-1-2
- Spectrum (ART 3.2) : ETSI EN 300 328 V2.1.1
  ETSI EN 301 489-1 V2.1.1
  ETSI EN 301 489-17 V3.1.1

SAS au capital de 5 180 800 € - Siret 310 967 294 000 52 – NAF 2660 Z – N° identification TVA : FR 29 310 967 294

SCHILLER MEDICAL
4, rue Louis Pasteur
67160 Wissembourg – France

Téléphone +33 (0) 3 88 63 36 00

Télécopie +33 (0) 3 88 94 12 82

Internet : http://www.schiller-medical.com
Email : info@schiller.fr

SCHILLER
MEDICAL

ENGAGEMENT

As responsible for Regulatory Affairs at SCHILLER MEDICAL, I hereby certify that:

- The product above fulfils the main requirements set out in Directive 93/42/CEE annex 1, chapter 1 to 13
- The product above fulfils the main requirements set out in Directive 2014/53/UE
- CE labelling will be fixed in accordance with directives used.

Wissembourg, April 26, 2021.

SCHILLER MEDICAL
4 rue Louis Pasteur
67160 WISSEMBOURG | FRANCE
Tél : +33 (0) 3 88 63 36 00

Valérie ENGEL
Regulatory Affairs manager

THE ART OF DIAGNOSTICS

SAS au capital de 5 180 800 € - Siret 310 967 294 000 52 – NAF 2660 Z – N° identification TVA : FR 29 310 967 294