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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

GMDN code: 61161

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

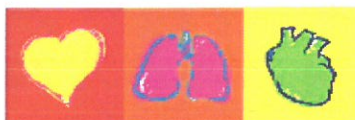
R : Respiration

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."



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			

Accessories included in the CE marking file

Code Article / Article Code SCHILLER MEDICAL	DESIGNATION
0-13-0051	Wireless ECG sensor W-ECG
0-13-0052	Wireless SpO2 adult sensor W-SA
0-13-0053	Wireless SpO2 child sensor W-SP
0-13-0060	Wireless SpO2 very small sensor W-SVS
9-01-0187	Temperature probe, based on optical principle, for external/skin application

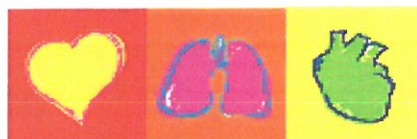
Accessories deliverable with the device

Article no.	Article description
ECG	
0-21-0046	ECG patch for MAGLIFE RT-1 W-ECG adult/child recommended for patient weight > 3 kg
0-21-0047	ECG patch for MAGLIFE RT-1 W-ECG neonate recommended for patient weight < 5 kg
NIBP	
U50143	Cuff for Neonatal soft, 2.5 cm
U50142	Cuff for Neonatal soft, 4 cm
0-04-0001	Cuff for Neonatal soft, 6 cm
0-04-0002	Cuff for Child, 8 cm



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0-04-0003	Cuff for Child, 10 cm
0-04-0004	Cuff for Adult, 14 cm
0-04-0005	Cuff for Adult, 17 cm
0-04-0006	Cuff for Adult, 20 cm
0-22-0003	Cuff pipe 5 m
IBP	
3-10-0221	Adaptor for BIOSENSORS sensors
3-10-0225	Adaptor for EDWARDS sensors
3-10-0224	Adaptor for BECTON DICKINSON sensors
3-10-0226	Adaptor for ABBOTT/ICU sensors
3-10-0232	Adaptor for BBRAUN sensors
3-10-0230	Adaptor for SMITH sensors
W1412109	Adaptor for MEDEX Logical sensors
3-10-0235	Adaptor for PVB Xtrans sensors
SpO₂	
0-13-0059	Spare SpO ₂ sensor for MAGLIFE RT-1 W-SVS (0-13-0060)
0-45-0004	Soft-wraps for very small SpO ₂ sensors (10 pcs)
Capnography	
6-14-0006	Airway T-Adapter (ordered in multiples of 100)
6-14-0101	Airway 90° adapter (ordered in multiples of 100)
0-40-0000	CO ₂ monitor Sample line adult/paediatric 3 meters (ordered in multiples of 25)
0-40-0001	CO ₂ monitor Sample line neonate 3,0 meters (ordered in multiples of 25)
4-72-0006	DRYLINE II water trap adult/paediatric
4-72-0005	DRYLINE II water trap neonate
0-32-0002	Calibration gas canister (MAGLIFE RT-1)
3-39-0076	Regulator for calibration gas
Basic Ventilation	
0-13-0056	SPIRIT Flow sensor, adult/paediatric, 3.3 meters, without gas sampling
0-13-0058	SPIRIT Flow sensor, paediatric/neonate, 3.3 meters, without gas sampling
0-13-0055	SPIRIT Flow sensor, adult/paediatric, 2.5 meters, with gas sampling
0-13-0057	SPIRIT Flow sensor, paediatric/neonate, 2.5 meters, with gas sampling



General accessories

4-15-0030	Mains cable 5 meters UK
4-15-0032	Mains cable 5 meters EU
U32010	Mains cable, 2P+PE, 2 meters CEE type
4-15-0009	Mains cable, 2P+PE, 5 meters CEE type
77323	Mains cable, 2P+PE, 5 meters US Type HG (Hospital Grade)
4-15-0082	Mains cable, 2P+PE, 5 meters UK type straight
72285	Mains cable, 2P+PE, 2 meters UK Type BS 1363/A (fused)
4-15-0067	Mains cable, 2P+PE, 5 meters Swiss/BR type straight
4-15-0068	Mains cable, 2P+PE, 1,8 meters Swiss/BR type straight
1-131-5881	MAGSCREEN RT-1
1-131-5581	MAGLINK
5-30-0023	Ethernet switch FO/RJ45 - 4 ports
5-30-0024	Wireless access point

NOTIFIED BODY

Numéro: 0459

Nom : GMED

Adresse: 1, rue Gaston Boissier 75724 PARIS CEDEX 15-France

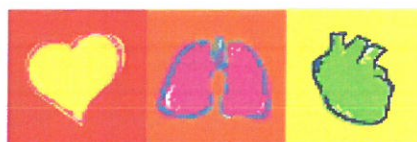
PROOF OF CONFORMITY WITH MAIN REQUIREMENTS WITH DIRECTIVES USED
Directive 93/42/CEE

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



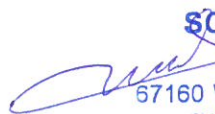
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ENGAGEMENT

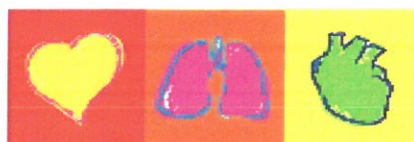
As responsible for Regulatory Affairs at SCHILLER MEDICAL, I hereby certify that:

- 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 5, 2023


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Valérie ENGEL
Regulatory Affairs Manager



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