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SCHILLER
MEDICAL

Declaration of conformity with directives 93/42/CEE and 2014/53/UE

File N°: CE ARE 0128A

Product

Name : **PHYSIOGARD Touch 7**

Function: **Multiparametric patient monitor**

Classification: **IIb** 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."

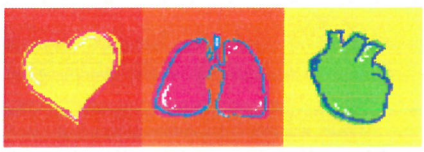
Number: **Composition of number 12895sxxxxxx**
128 : project number of the device
12895 : PHYSIOGARD Touch 7
s : Device serial number
xxxxxx :Unit number

MANUFACTURER

Manufacturer's address: 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 60601-1-12
IEC 60601-2-25
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



THE ART OF DIAGNOSTICS

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SCHILLER
MEDICAL

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: GMED certificate CE n° 23223 rev.9 issued on April 21, 2021.

Directive 2014/53/UE
Standards applied on
- Safety and health (ART 3.1.a): serial IEC 60601
- CEM (ART 3 .1b) : IEC 60601-1-2
- Spectrum (ART 3.2) : ETSI EN 301 489-1 V1.9.2 ETSI EN 301 489-7 V1.3.1
  ETSI EN 301 489-24 V1.5.1 ETSI EN 300 328 V1.8.1
  ETSI EN 302 291-1 V1.1.1 ETSI EN 302 291-2 V1.1.1
  ETSI EN 301 489-1 V1.9.2 ETSI EN 301 489-17 V2.1.1

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 appendix I, chapter 1 to 13
- The product above fulfils the main requirements set out in Directive 2014/53/UE
- CE labelling will be affixed in accordance with directives used.

Wissembourg, May 06, 2021

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Valérie ENGEL
Regulatory Affairs manager