

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

**File N°: CE ARE 0128**

### Product

Name: **DEFIGARD Touch 7**

Function: **Defibrillator with monitor**

Classification: **IIb** in accordance with rule 9 below of classification of medical device of Directive 93/42/CEE

"All active therapeutics devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, density and site of application of the energy, in which case they are in Class IIb.

All active devices intended to control or monitor the performance of active therapeutic device in Class IIb, or intended directly to influence the performance of such devices are in Class IIb."

Number: **Composition of the number 12899sxxxxxx or 12896sxxxxxx**

**128** : project number of the device

**12899**: DEFIGARD Touch 7

**12896**: DEFIGARD 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 60601-2-4

IEC 60601-2-25

IEC 60601-2-27

IEC 80601-2-30

IEC 60601-2-34

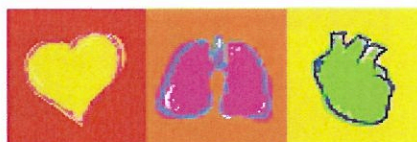
IEC 60601-2-49

IEC 80601-2-55

IEC 80601-2-56

IEC 80601-2-61

NF EN 1789



**THE ART OF DIAGNOSTICS**

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## Accessories

Article no.	Article description
<b>Device</b>	
3.940100	Battery Li/ion 11.1V, 4.65 Ah, 51.6 Wh(rechargeable)
4-07-0022	Battery Li/MnO2, 6 V, 1,4 Ah
<b>ECG</b>	
0-05-0072	ECG PATIENT CABLE "6 IN 4" IEC, PRESS STUDS ANGLED main cable with 4 leads 1.05 m
0-05-0073	ECG PATIENT CABLE "6 IN 4" IEC, MEDICLIP ANGLED main cable with 4 leads 1.05 m
2.410079	6-pol. Leadset extension cable, MEDICLIP type, IEC
0-05-0052	6-pol. Leadset extension cable, press stud type, IEC
0-05-0065	ECG PATIENT CABLE "6 IN 4" AHA, MEDICLIP ANGLED main cable with 4 leads 1.05 m
0-05-0066	6-pol. Leadset extension cable, MEDICLIP, AHA
0-05-0076	ECG PATIENT CABLE "6 IN 4" AHA, PRESS STUDS ANGLED main cable with 4 leads 1.05 m
0-05-0077	6-pol. Leadset extension cable, PRESS STUDS, AHA
-	ECG electrodes pouch: SCHILLER recommends using ECG electrodes with liquid gel (e.g Ambu® BlueSensor or Medico electrodes MLGLT-03)
<b>NIBP</b>	
0-04-0012	Cuff for neonatal soft, 4 cm (Arm circumference 6-12 cm)
0-04-0016	Cuff for Child, 8 cm (Arm circumference 11-22 cm)
0-04-0014	Cuff for Child, 11 cm (Arm circumference 16-28 cm)
0-04-0013	Cuff for Adult, 13 cm (Arm circumference 26-33 cm)
0-04-0017	Cuff for Adult, 15 cm (Arm circumference 33-41 cm)
0-04-0015	Cuff for Adult, 19 cm (Arm circumference 39-55 cm)
0-87-0006	Hose assembly NIBP, 2 m
<b>SpO2</b>	
2.310301	Connection cable SpO2 Masimo 1.2 m
2.100598	Adult (> 30 kg) reusable finger clip sensor, 1m, M-LNCS DCI
2.100565	Adult (> 30 kg) soft reusable finger clip sensor, 1m, M-LNCS DBI
0-13-0031	Paediatric/slender (10-50 kg) reusable finger clip sensor, 1 m, M-LNCS DCIP



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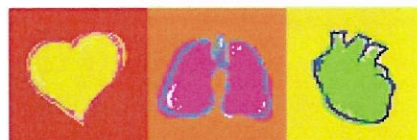
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Article no.	Article description
2.100627	Disp. adult (> 30 kg) adhesive finger sensor, 1m, 20/box, M-LNCS ADTX-3
2.100628	Disp. paediatric (10-50 kg) adhesive finger sensor, 1m, 20/box, M-LNCS PDTX-3
2.100629	Disp. infant (3-20 kg) adhesive sensor, 1m, 20/box, M-LNCS INF-3
2.100630	Disp. neonatal/adult (< 3 kg or > 40 kg) SpO2 adhesive sensor, 1m, 20/box, M-LNCS NEO-3
<b>SpCO, SpMet, SpO2</b>	
2.310301	Connection cable SpO2 1.2 m
2.100599	Adult (>30 kg) reusable finger clip sensor, 1m, Rainbow DCI
0-13-0033	Paediatric (10-50 kg) reusable finger sensor, 1m, Rainbow DCIP
<b>Temp</b>	
2.101108	Reusable temperature probe rectal / oesophageal, adult, 2m
2.101109	Reusable temperature probe rectal / oesophageal, child, 2m
2.101104	Temperature probe skin adult
2.310298	Reuseable connecting cable for disposable temperature probe
<b>CO2 IRMA/ISA</b>	
2.100571	IRMA CO2 sensor
6-17-0015	Trunk cable IRMA etCO2 with adapter plate
2.101176	ISA sidestream etCO2 sensor
6-17-0024	Trunk cable ISA etCO2 with adapter plate
<b>IBP</b>	
2.310285	IBP cable assembly Braun
2.310297	IBP cable assembly Baxter
2.310299	IBP cable assembly Transpac IV
2.310164	IBP cable assembly Utah, Mallinckrodt
2.310308	IBP cable assembly PCB Combitrans
2.310296	IBP cable assembly Ohmeda
2.310246	IBP cable assembly Medex
<b>DEFI</b>	
<b>DEFIGARD<sup>®</sup> Touch 7</b>	
0-21-0040	1 pair disposable adhesive defibrillation electrode pads for adults, 80 cm <sup>2</sup> pre-connected with RFID
2.155067	1 pair of disposable adhesive defibrillation pads for children, 42 cm <sup>2</sup>
2.100860	ARGUS LifePoint (CPR feedback sensor)
6-17-0012	Adapter cable for LifePoint CPR feedback sensor
2.100519	Adhesive pad set of 5 pcs
0-05-0064	Pads adapter connector BigSPC-P to connector type SPC-D



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<b>General accessories</b>	
0-80-0023	Carrying bag
3.940100	Li/Ion 11.1 V, 4.65 Ah, 51.6 Wh (rechargeable)
1-128-5081	Ambulance bracket with <b>AC/DC</b> charging module. The battery is charged in the device via ambulance bracket.
1-128-5780	Ambulance bracket with <b>DC/DC</b> charging module. The battery is charged in the device via ambulance bracket.
1-128-5180	<b>Desktop</b> bracket with <b>AC/DC</b> charging module. The battery is charged in the device via Desktop bracket.
1-128-5181	Nomad <b>AC/DC</b> charging module
2.100018	Charging unit CS-1, external battery charger
1-128-5183	Stretcher bracket

## 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° 23213 rev 9 issued 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 301 489-24 v1.5.1
  - ETSI EN 301 489-7 v1.3.1
  - ETSI EN 301 489-1 v1.9.2
  - ETSI EN 300 328 V1.8.1
  - ETSI EN 302.291-1 V1.1.1
  - ETSI EN 302 291-2bV1.1.1
  - ETSI EN 301 489-17 v2.1.1
  - ETSI EN 301511 (partial test)
  - ETSI 151010-1 (partial test)



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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 appendix I, 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, November 17, 2021

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Valérie ENGEL  
Regulatory Affairs Manager



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