SLG Prüf- und Zertifizierungs GmbH

ASSESSMENT REPORT

5021-14-PP-15-BB005

Product / UMDNS	**Public Access Defibrillator (battery powered) / 11-134**
Class according MDD, Annex IX ...	**IIb**
Manufacturer.....	**CARDIA INTERNATIONAL A/S** **Hersegade 20** **4000 Roskilde, Denmark**
Assembler.....	**Corscience GmbH & Co. KG** **Hartmannstraße 65** **91052 Erlangen, Germany**
SLG – Scope of Accreditation	**MD1103 Stimulators, acupuncture equipment and defibrillators**
Model / Type ref. / Serial-No......	**CardiAid CT0207RS; CardiAid CT0207RF**
Technical Data and Documents	**Operating mode Semi-automatic (*RS), Full-automatic (*RF)** **270 J/ 170 J (Adult), 75 J/ 50 J (Child); IP55; 5 °C ... 50 °C;** **ECG-analysis-time < 10 s, recovery-time < 20 s;** **shock capacity up to 210 shocks (minimum 100 shocks);** **Battery pack CA-4BP: 12 V, 15 Ah Alkaline, fused 15 A;** **"User Manual and Introduction to the Device for models CT0207RS and CT0207RF", CD02MNL001 v.3.0.40403 & v3.0.41107,** **languages EN, FR, DE, NL; Bluetooth for service only;** **Firmware Version 6;** **Disposable electrodes CA-10ES (adult), CR-13P (child)** **with Shelf Life 30 (adult), 18 (child) month from date of maufacture**
Trade mark	**CardiAid**
Additional information	**adult (> 8 years / 25 kg); child (1-8 years / < 25 kg);** **Emergency kit CT0207EK (disposable, not sterile with razor scissors, CPR mask, gloves, alcohol pad) not certified;** **Validation documents of improved firmware version 6 accepted and confirmed by manufacturer**
Recommended Period of Validity ...	**2019-05-26**
Sample of product has been tested and found to be in conformity with..	**Evaluation Plan 5057-13-PP-14-BL001** **93/42/EWG, Annex III**
Test Protocol no(s).	**5057-13-PP-13-PP001 (IEC 60601-1),**
Test Reports	**5057-13-PP-13-PP002 (IEC 60601-2-4),** **5057-13-PP-13-PP003 (IEC 60601-1-6),** **5057-13-PP-13-PP005 (IEC 62366)**
Test and Assessment Reports	**5057-13-PE-14-PB001 (EMC according to EN 60601-2-4:2011)**
Document Evaluation no(s).	**5021-14-PP-14-DR001, 5021-14-PP-14-DR002** **5021-14-PP-14-DR003, 5080-15-PP-15-DR003**

Above mentioned test specimen was representative for the product an in accordance with the relevant provisions of the Medical Device Directive 93/42/EEC for the described device type.

Hartmannsdorf, 7th of October 2015

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