EC Certificate Full Quality Assurance System: Certificate KR05/64342

The management system of

Charmcare Co., Ltd.

(Gasan-dong, Woolim Lions2-cha), 714, 2, Gasandigital1-ro,
Geumcheon-gu, Seoul, Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Pulse oximeter (Model: CX100, ACCURO, Charm II):
Reusable pulse oximeter sensor (Model: ACCY-0A0PRB):
Pulse oximeter (Model: CX120, CX130, RAPIDO II, C30):
Reusable multi-site oximeter sensor (Model:ACCY-0C0PRB):
Reusable neonatal oximeter sensor (Model:ACCY-0D0PRB):
Patient Monitor (Model: CX210, PRIZM5, PRIZM7M, PRIZM7S, PRIZM 3)

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

This certificate is valid from 20 June 2014 until 3 March 2019 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 February 2017
Issue 16. Certified since 3 March 2005

Certification is based on reports numbered WW/PCI 211537

Authorised by

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