EC Certificate Full Quality Assurance System: Certificate KR05/64342

The management system of

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Date: 2021.06.26 12:18:57 EEST
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Location: Moldova

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, CX150):
Reusable pulse oximeter sensor
(Model: ACCY-0A0PRB, ACCY-0A6PRB):
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)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 6 April 2017 until 3 March 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 February 2020
Issue 19. Certified since 3 March 2005

Certification is based on reports numbered WW/PCI 211537

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
.t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

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