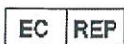


EC Declaration of Conformity



Manufacturer : Charmcare Co., Ltd.

(Gasan-dong, Woolim Lions2-cha), 714, 2, Gasandigital 1-ro, Geumcheon-gu, Seoul, Korea



European representative :

TECNOMED 2000 C/Palos de la Frontera, 4, 3º 28012 - Madrid Spain

Product : Pulse Oximeter, Reusable pulse oximeter sensor

Model : CX130, ACCY-0A0PRB

Classification : Class IIb (Council Directive 93/42/EEC as amended by Directive 2007/47/EC, Annex IX Rule 10)

Conformity Assessment Route : Annex II, Excluding Section 4, Council Directive 93/42/EEC as amended by Directive 2007/47/EC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.



0120

Notified Body : SGS united kingdom Limited
Unit 202B, Worle Parkway Weston-Super-Mare Somerset
BS22 0WA United Kingdom

Identification Number (EC) Certificate(s) KR05/64342

Valid Date : 9 March 2016

Expiry Date : 3 March 2019

Standards applied : EN ISO 13485:2012, EN ISO 14971:2012, EN 1041:2008+A1:2013, EN 9001:2008 EN 980:2008,
EN 60601-1:2006+A1:2013, EN 60601-1-2:2007, EN 60601-1-6:2010, EN ISO 10993-1:2009,
EN ISO 14155-1:2012, EN 62304:2006, EN 60601-1-8:2007, ISO 80601-2-61:2011,
EN 50419:2005

Start of CE-Marking : 3 March 2005

Place, Date of issue : Seoul, Korea 20 Jan 2017

Signature:

Charmcare Co., Ltd.


President / Donghwa-Lee

President

on behalf of Charmcare Co., Ltd.