

Document Number	Revision	ECO Number	Effectivity Date
DOC 019	01	1241531	05 Oct 2012
DOC 019	00	1202012	27 Jan 2012

EC Declaration of Conformity

ClearStream Technologies Ltd.
Upper Moyne
Enniscorthy
County Wexford
Ireland

Declares that the medical device Class IIa described hereafter

The **Renma** PTA Balloon Catheter

Part Numbers 135cm Shaft	Balloon Length (mm)				
Balloon Diameter (mm)	20	40	60	80	100
4.0	BD-C40201DN	BD-C40401DN	BD-C40601DN	BD-C40801DN	BD-C40A01DN
5.0	BD-C50201DN	BD-C50401DN	BD-C50601DN	BD-C50801DN	BD-C50A01DN
6.0	BD-C60201DN	BD-C60401DN	BD-C60601DN	BD-C60801DN	BD-C60A01DN
7.0	BD-C70201DN	BD-C70401DN	BD-C70601DN	BD-C70801DN	BD-C70A01DN
8.0	BD-C80201DN	BD-C80401DN	BD-C80601DN		
9.0	BD-C90201DN	BD-C90401DN	BD-C90601DN		
10.0	BD-CA0201DN	BD-CA0401DN	BD-CA0601DN		

is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended, is subject to the procedure set out in the Annex II of the directive 93/42/EEC under the supervision of the notified body number 0344, DEKRA Certification B.V., Utrechtseweg 310, 6812 AR Arnhem, P.O. Box 5185, 6802 ED Arnhem, The Netherlands.

Certificate Number: 2097655CE07

GMDN Code (preferred term): 17184

MASTER

Signature: *Fiona Ní Mhulláin* **Date:** 05-OCT-12
Fiona Ní Mhulláin
Senior RA/QA Manager
on behalf of ClearStream Technologies Ltd.