

EC Declaration of Conformity

ClearStream Technologies Ltd.
 Moyne Upper
 Enniscorthy
 County Wexford
 Ireland

Declares that the medical device **Renma PTA Dilatation Catheter**, is classified as a Class IIa device in accordance with Annex IX of MDD 93/42/EEC, as amended, Rule 6.

Table1: Renma PTA Dilatation Catheter 135cm shaft product codes

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		

VAT No. IE 8250810E, Directors: P. Oakes (Director of Operations), J. Spicer, D. Wheal
 Registered No.: 250810. Registered Office: Moyne Upper, Enniscorthy, Co. Wexford, Ireland.

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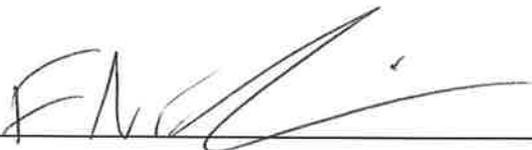
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The Renma PTA Dilatation Catheter is in conformity with the essential requirements of Annex I and provisions of the Council Directive 93/42/EEC of 14 June 1993, as amended, is subject to the procedure set out in the Annex II of the directive 93/42/EEC under the supervision of the notified body number 0344, DEKRA Certification B.V., Meander 1051, 6825 MJ Arnhem, The Netherlands.

QSM Certification: 2087517
Certificate Number: 2097655CE07
GMDN Code (preferred term): 17184

The Renma PTA Dilatation Catheter was first CE Marked in July 2011.

Signature:



Date:

03 Feb 16

Fiona Ní Mhulláin

Senior RA/QA Manager

on behalf of ClearStream Technologies Ltd.

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