ECM Europe BV
Oost-Om 54, 5422 VZ Gemert
P.O. Box 53, 5420 AB Gemert
T. +31 (0)492 37 12 34
F. +31 (0)492 37 12 37
info@ecmbv.nl - www.ecmbv.nl

Account nr. 6466958
Bank: ING Bank N.V.
IBAN: NL46INGB0006466958
Swift address: INGBNL2A
VAT no. NL8502.44.754.B.01
C.o.C. Eindhoven no. 51966360

DECLARATION OF CONFORMITY MEDICAL DEVICES

We hereby declare that the distributed CE marked products, specified in the annexed product-list, are covered by the "CE Marking of Conformity Certificate", reference number 2144240CE01, first issued April 18, 2011, delivered by Dekra Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, and conform to the required technical documentation, in accordance with Annex VII of the law "Besluit Medische Hulpmiddelen" of The Netherlands transposing the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa, according to Annex IX, rule 2, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality Management System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex V and VII of the Directive. The conformity as set out in these Annexes, is described in the said CE Marking of Conformity Certificate, issued and delivered by Dekra Certification B.V.

This declaration is supported by the Quality Management System certification based on the standard ISO 13485:2016, delivered by Dekra Certification B.V.

This declaration of Conformity covers the following device(s):

Medical Tubing Systems and Accessories for the purpose of extra-corporeal blood circulation, monitoring and transportation

and is valid for all products concerned bearing the CE Marking, manufactured at the following sites:

ECM Europe BV
Oost-Om 54
5422 VZ Gemert

Signed by: P.M.L.M. Kanters
QA Manager

Gemert, April 1, 2020

The Product-list is only available after written request.