



MEDICARE UITGEEST B.V.

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Declaration of Conformity medical devices

We hereby declare that the distributed CE-marked products, specified in the product list, are covered by the 'CE Marking of Conformity Certificate' with reference 2110398CN re-issued on February 1 2016 by the notified body: DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem, Netherlands, with notified body identification number 0344.

The products conform to the required technical documentation in accordance with annex VII of the Dutch law "Besluit Medische Hulpmiddelen" transposing the European Community Directive as the Council Directive 93/42/EEC of 14th June 1993 and Directive 2007/43/EG on medical devices.

We declare that the CE marked products mentioned in the certificate meet the applicable provisions of the European Community Directive for Class IIa devices.

This declaration is based on the application of the Quality System approved for the manufacturing and final inspection of the products listed in accordance with Annex V of the European Community Directive for medical devices. Conformity of Product quality assurance stated in Annex V is confirmed by the CE Marking of Conformity certificate as issued by DEKRA Certification B.V.

The following standards have been used for the products below:

NEN-EN-ISO 10079-3:2014	Medical suction equipment - Suction equipment powered from a vacuum or positive pressure gas source
NEN-EN-ISO 5359:2014	Low pressure hose assembly for use with medical gases
NEN-EN-ISO 18082:2014	Anaesthetic and respiratory equipment - Dimensions of noninterchangeable screw-threaded (NIST) low-pressure connectors for medical gases

Product list:

Name	Model	Serialnumbers and higher
Medicare Vacuümregelaar	Starting with 0301xxxx	0372568
Medicare Vacuüminjecteur	Starting with 0302xxxx	0382584
Medicare Vacuüminjecteur (Thorax)	Starting with 03006xxx	
Slangstellen	Starting with 07000xxx	0614983

F. Wilms
Managing Director