

CERTIFICATE

Number: 2020037CE02

CE MARKING OF CONFORMITY MEDICAL DEVICES

Issued to:

Inpakomed BV
Industrieweg 13a
1566 JN Assendelft
The Netherlands

For the product category:

Sterile vial ventilation systems

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2020037CN, initially dated 15 June 2002
Addendum, initially dated 31 July 2013

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex V in combination with Annex VII for class Is products, is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. The necessary information and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 February 2017
Issued for the first time: 31 July 2013
Reissued: 1 February 2014

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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ADDENDUM

Belonging to certificate: 2020037CE02

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CE MARKING OF CONFORMITY MEDICAL DEVICES

Sterile vial ventilation systems

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The Netherlands

This certificate covers the following product(s):

PharmaVent - Aeration needle

Initial date: 31 July 2013

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan
Certification Manager

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