

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer: Innoventa Medica ApS
Blokken 45, DK-3460 Birkerød
Denmark

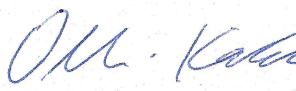
Coverage of Certificate: Design, manufacture and final inspection

Product category: Sterile single-use devices for
surgical aspiration procedures


Valid until: 27th May 2024

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex II Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex II in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Valid from: 13th January 2020



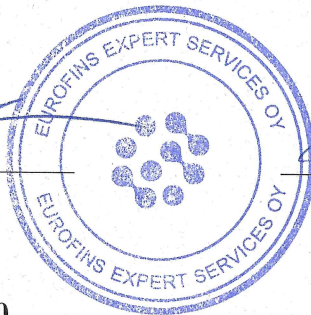
Olli Kakkonen



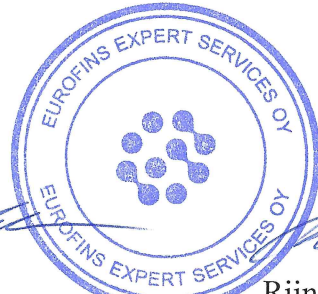
Riina Uusmies

Certificate no.
C-01-1209-720-20

Notified Body no. 0537:
Eurofins Expert Services
Kivimiehentie 4
FI-02150 ESPOO, FINLAND



Attachment 1 to the Certificate number: C-01-1209-720-20

Manufacturer:	Innoventa Medica ApS Blokken 45, DK-3460 Birkerød Denmark				
Activity and product category:	Design, manufacture and final inspection of sterile single-use devices for surgical aspiration procedures GMDN-code(s): 60793				
Products:	<p>The certificate covers the following products:</p> <table border="0" style="width: 100%;"> <thead> <tr> <th style="text-align: left;"><i>Name</i></th> <th style="text-align: right;"><i>Class</i></th> </tr> </thead> <tbody> <tr> <td>Seroma Set™</td> <td style="text-align: right;">Is</td> </tr> </tbody> </table>	<i>Name</i>	<i>Class</i>	Seroma Set™	Is
<i>Name</i>	<i>Class</i>				
Seroma Set™	Is				
Date:	Valid from: 13 th January 2020 <div style="text-align: center;">  <i>Olli Kakkonen</i> Olli Kakkonen </div> <div style="text-align: right; margin-top: 20px;"> <i>Riina Uusmies</i> Riina Uusmies </div>				

Eurofins Expert Services is Notified Body no. 0537 under Council Directive 93/42/EEC.

EUROFINS EXPERT SERVICES

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Business ID FI22975132