

## MDD Art.12 - DECLARATION

1) Producer :

Name: **Giskit B.V.**

Address: Beursplein 37, WTC Rotterdam - Suite 1960, 3011 AA Rotterdam, The Netherlands

Contact: tel: +31 10 2619100

e-mail: info@iq-medicalventures.com

2) Product(s) (name, type or model/batch number, etc.) and device names:

See appendix

3) The product(s) described above (is)are in conformity with:

Document Nr.	Title	Edition / Date of issue
Medical Device Directive	93/42/EEC, art. 12	1993-06-14

4) Additional information:

- Producer has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions and the production is carried out in accordance with these instructions; and
- Producer has packaged the set and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
- The whole production is subjected to appropriate methods of internal control and inspection.
- Registration with Dutch Competent Authorities on: July 08, 2020

Rotterdam, NL; 2020-07-08

Place & date of issue (yyyy-mm-dd)

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L. van der Hoek, Director, GISKIT B.V.

name; function and signature of manufacturer

Rotterdam, NL; 2020-07-08

Place & date of issue (yyyy-mm-dd)

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L. van der Hoek, Director, GISKIT B.V.

name; function and signature of authorized representative

<b>Giskit B.V.</b>	<i>Art. 12 - Declaration</i>	Document: D-art12 2007v01
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## **Appendix**

Date: July 08, 2020

### List of systems / procedure packs / sets

<b>Product Name</b>	<b>type/model/ref number of CE-marked devices</b>	<b>First date</b>
ExEm® Foam Kit FK05	<ul style="list-style-type: none"> <li>• 10 ml syringe with 5 ml ExEm® Gel / 343046 (Giskit B.V.)</li> <li>• 10 ml syringe with 5 ml ExEm® Water (purified water) / 342056 (Giskit B.V.)</li> <li>• coupling device / 5206634 (B. Braun Melsungen AG)</li> </ul>	September 10, 2014
ExEm® Foam Kit FK05-LM969	<ul style="list-style-type: none"> <li>• 10 ml syringe with 5 ml ExEm® Gel / 343046 (Giskit B.V.)</li> <li>• 10 ml syringe with 5 ml ExEm® Water (purified water) / 342056 (Giskit B.V.)</li> <li>• coupling device / 5206634 (B. Braun Melsungen AG)</li> <li>• GIS catheter / #5165-LM969 (Gynétics Medical Products N.V.)</li> </ul>	September 10, 2014
ExEm® Foam Kit FK05-LN970	<ul style="list-style-type: none"> <li>• 10 ml syringe with 5 ml ExEm® Gel / 343046 (Giskit B.V.)</li> <li>• 10 ml syringe with 5 ml ExEm® Water (purified water) / 342056 (Giskit B.V.)</li> <li>• coupling device / 5206634 (B. Braun Melsungen AG)</li> <li>• GIS catheter / #5165-LN970 (Gynétics Medical Products N.V.)</li> </ul>	September 10, 2014