



**GISKIT B.V.**  
**DECLARATION OF CONFORMITY**

We  
GISKIT B.V.  
World Trade Center Rotterdam  
Beursplein 37, Suite 1960  
3011 AA Rotterdam  
The Netherlands

hereby declare in our own responsibility that the product

**ExEm<sup>®</sup> Water (5 ml)**

water to dilute ExEm<sup>®</sup> Gel for tissue distension for diagnostic gynecological  
ultrasound imaging of the female reproductive tract

is in compliance with the following directive

Council Directive 93/42/EEC of June 14th 1993

concerning Medical Devices amended by Directive 2007/47/EC

and EN ISO 13485:2016  
and EN ISO 17665-1:2006

**Conformity assessment procedure**

according to Annex V of the council directive

named above

This declaration is valid in connection with the relevant batch-related release  
documentation only.

Product number: 342056  
Classification: Risk Class Is, rule 5  
Notified Body: DNV GL Presafe AS  
Number 2460

Date of first CE-marking: March 2, 2020      Valid until: May 27, 2024  
Certificate No.: 10000325577-PA-NA-CZE

Rotterdam, March 17, 2020  
GISKIT B.V.

L. van der Hoek  
QARA and Legal Affairs Director