



GISKIT MD B.V.

## DECLARATION OF CONFORMITY

We  
GISKIT MD B.V.  
Veerkade 5 F  
3016 DE Rotterdam  
The Netherlands

hereby declare in our own responsibility that the product

### **ExEm<sup>®</sup> Water (5 ml)**

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 26, 2024  
Certificate No.: 10000325577-PA-NA-CZE

Rotterdam, September 16, 2021  
GISKIT MD B.V.

L. van der Hoek  
QARA and Legal Affairs Director