

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.: 10000325577-PA-NA-CZE

Valid Until: 27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:

Giskit B.V.

originally issued in compliance with:

the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment and/or audit performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

The name of the manufacturer has changed to Giskit MD B.V. The Head office has been relocated.

The site name has also changed. The site has also been relocated.

Sites covered by certificate (replaces information on certificate)		
Giskit MD B.V.	Head office: Veerkade 5 F, 3016 DE Rotterdam, The Netherlands	
	Site address: Lagosweg 63, 2622 CZ Delft, The Netherlands	

Appendix History -		
Revision	Description	Issued Date
0.0	Original Appendix – the name and the address of the manufacturer has changed, and the site name and the site address has changed.	08 November 2021
1.0	Adding Head office address	12 November 2021
2.0	Administrative correction	06 December 2021

Place and date:
Hevik 06 December 2021

For the issuing office: DNV Product Assurance AS - Notified Body 2460 Veritasveien 3, 1363 Høvik, Norway

Tone Kolpus Lead Auditor