

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
11491-2017-CE-IND-NA-PS Rev. 2.0

Valid Until:
26 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
Primus Gloves Private Limited

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.

A new EU representative, replacing the one stated on the certificate, has been accepted.

EU Representative
Amstermed BV, Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands

Appendix History -		
Revision	Description	Issued Date
0.0	Brand addition in bold	19 July 2021
1.0	EU representative changed	09 September 2022

Place and date:
Høvik, 09 September 2022

For the issuing office:
DNV Product Assurance AS - Notified Body
2460
Veritasveien 1, 1363 Høvik, Norway



Mariann Jeremiassen
Principal Assessor