Certificate

Certificate

24M00174CRT01

First issue	17-Jun-2025	Re-certification	Not Applicable
Reissued	Not Applicable	Preceeding cert.	Not Applicable
Valid until	17-Jun-2030		

EU Quality Management System Certificate – Annex IX

Conformity Assessment Based on a Quality Management System
and on Assessment of Technical Documentation
Regulation 2017/745 on MEDICAL DEVICES

For the Quality Management System of

Plastiflex Group NV

Regarding the scope EU quality management system for the following devices or groups of devices: Active non-implantable respiratory devices.

This certificate is based on the following documents:

Audit report:	22M00174RPT01
Supplier audit report:	24M00141RPT01
TD report:	24M00005RPT01

Kiwa Assurance B.V. hereby declares that it has audited the quality assurance system in accordance with MDR Annex IX, chapter I and III and that the relevant provisions of the Regulation 2017/745 dated May 5, 2017 concerning Medical Devices are fulfilled. The validity of this certificate is Five (5) years and includes the surveillance obligations of Annex IX, section 3. The products shown in the scope of certification are covered by this certificate and may bear the CE marking using the Notified Body number “1912”.

Signed by:
N. Vazirpanah
2942F7C5177B433...
Dr. N. Vazirpanah
Certification Decision Maker

Signed by:
Dennis van der Vlugt
4F831C843C0B4EA...
Ing. D. van der Vlugt
Director

This certificate consists of 2 page(s)
Disclosure of the certificate is permitted

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Belgium
SRN: BE-MF-000008049

Certificate

Appendix of EU Quality Management System Certificate – Annex IX

The certificate 24M00174CRT01

The scope of certificate comprises an EU Quality Management Assessment regarding the following device(s):

Devices	Risk classification	Marketed under tradename	Intended purpose (only IIb and III)
Hybernite Basic UDI-DI: 5404013000000000000169 MDA 0307 Active non-implantable respiratory devices	Devices in Class IIa	Hybernite	NA
Hybernite RT Basic UDI-DI: 540401300000000000026B MDA 0307 Active non-implantable respiratory devices	Devices in Class IIa	Hybernite RT	NA

Revision History

Version	Changes
24M00174CRT01	Initial version

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