Certificate

Certificate
22M00079CRT02

First issue	16-Apr-2025	Re-certification	Not Applicable
Reissued	06-Nov-2025	Preceeding cert.	22M00079CRT01
Valid until	16-Apr-2030		

EU Quality Management System Certificate – Annex IX

Conformity Assessment Basedon aQuality ManagementSystem andonAssessment ofTechnicalDocumentation Regulation 2017/745 on MEDICAL DEVICES

For the Quality Management System of

Tyromotion GmbH

Regarding the scope EU quality management system for the following devices or groups of devices:

- Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport
- Software

This certificate is based on the following documents:

Audit report:	22M00079RPT01
TD report:	23M00116RPT01
TD report:	23M00117RPT01
TD report:	P000529111RPT01
Addendum:	25M00178ADD02
Addendum:	25M00179ADD01
Addendum:	25M00180ADD02

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”.

DocuSigned by:
704D97E19E3A471...
Dr. Ir. W. Wunderink
Certification Decision Maker

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

kiwa
MDR 2017/745

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

Kiwa Assurance B.V. (Kiwa Medical Certification)
Vijzelmolenlaan 7
3447 GX Woerden
The Netherlands
T. +31 348 200 980
nl.nboffice@kiwa.com
www.kiwapid.eu

Tyromotion GmbH
Bahnhofgürtel 59
8020 Graz
Austria
SRN: AT-MF-000016168

Certificate

Appendix of EU Quality Management System Certificate – Annex IX

For the certificate 22M00079CRT02

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)
Amadeo 912007718AMADEO3J MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Devices in Class IIa	Amadeo	NA
TyroS 912007718TYROSG7 MDA 0315 Software	Devices in Class IIa	TyroS	NA
Lexo 912007718LEXOBB MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Devices in Class IIa	Lexo	NA
Omego 912007718OMEGO8T MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Devices in Class IIa	Omego	NA
Diego 912007718DIEGO46 MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Devices in Class IIa	Diego	NA

Revision history

Version	Changes
22M00079CRT01	Initial version
22M00079CRT02	Addition of devices: Lexo, Omego and Diego

Kiwa Assurance B.V. (Kiwa Medical Certification)
Vijzelmolenlaan 7
3447 GX Woerden
The Netherlands
T. +31 348 200 980
nl.nboffice@kiwa.com
www.kiwapid.eu

Tyromotion GmbH
Bahnhofgürtel 59
8020 Graz
Austria
SRN: AT-MF-000016168