tyromotion
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# Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

| | |
|---|---|
| Manufacturer name | Tyromotion GmbH |
| Manufacturer address and contact details | Bahnhofgürtel 59, 8020 Graz, AUT |
| Single Registration Number (SRN) (if available) | AT-MF-000016168 |

| | |
|---|---|
| Notified body name (if applicable) | DQS Medizinprodukte GmbH |
| Notified body number (if applicable) | 0297 |
| Directive Certificate number(s) to which this confirmation is made (if applicable) | Certificate registration no.: 459933 MR2<br>Certificate unique ID: 170769922 |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | 2024-01-03 |
| End date of extended validity/transition period | 2028-12-31 |

*See also attached schedule for details of individual device identification on same directive certificate

Notified Body (Kiwa Dare B.V.) – Manufacturer (Tyromotion GmbH) Contract Date: 2022-06-01 (sign date)

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate** as listed in the attached schedule

- Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

  Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

- A notified body has issued the certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

**Signed for and on behalf of the manufacturer:**

Tyromotion GmbH

Graz, 28. December 2023

tyromotion
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Sabine Seereiner
Head of QM & RA

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

**Schedule of Devices**

The above Manufacturer's Declaration is valid for the following devices:

| **Identification of the device(s)**[3] (e.g., device name, family/group name device model or catalogue number) | **Directive Certificate number(s) to which this confirmation is made** (if applicable) | **Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable) | **Notified Body name and number that issued the Directive Certificate** (if applicable) | **Notified Body name and number where the MDR application was lodged/contract signed** (if applicable) | **End date of extended validity / transition period** | **Substitute Device(s)** (if applicable) |
|---|---|---|---|---|---|---|
| **Rehabilitation device for hands**<br><br>**Device: AMADEO** | **459933 MR2**<br><br>Certificate Unique ID: 170769922 | **2024-01-03** | **DQS Medizinprodukte GmbH, 0297** | **Kiwa Dare B.V., 1912** | **2028-12-31** | |
| **Arm-Therapy-System**<br><br>**Device: DIEGO** | **459933 MR2**<br><br>Certificate Unique ID: 170769922 | **2024-01-03** | **DQS Medizinprodukte GmbH, 0297** | **Kiwa Dare B.V., 1912** | **2028-12-31** | |
| **TyroS Software** | **459933 MR2**<br><br>Certificate Unique ID: 170769922 | **2024-01-03** | **DQS Medizinprodukte GmbH, 0297** | **Kiwa Dare B.V., 1912** | **2028-12-31** | |
| **Lower Limb Rehabilitation System**<br><br>**Devices:**<br>**OMEGO**<br>**LEXO** | **459933 MR2**<br><br>Certificate Unique ID: 170769922 | **2024-01-03** | **DQS Medizinprodukte GmbH, 0297** | **Kiwa Dare B.V., 1912** | **2028-12-31** | |

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)