Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and/or
- 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 | Medical Wire & Equipment Co (Bath) Ltd |
| Manufacturer address and contact details | Leafield Industrial Estate Potley Lane,<br>Corsham, Wiltshire SN13 9RT |
| Single Registration Number (SRN) (if available) | GB -MF-000006736 |

| | |
|---|---|
| Authorised Representative name (if applicable) | Advena Limited |
| Authorised Representative address and contact details | Tower Business Centre, 2nd Floor<br>Tower Street<br>Swatar<br>BKR 4013<br>Malta. |
| Single Registration Number (SRN) (if available) | MT-AR-000000234 |

| | |
|---|---|
| Notified body name (if applicable) | □ See attached schedule |
| Notified body number (if applicable) | □ See attached schedule |
| Directive Certificate number(s)<br>to which this confirmation is made (if applicable) | □ See attached schedule |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | □ See attached schedule |
| End date of extended validity/transition period | □ See attached schedule |

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
- 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(s) as listed above or in the attached schedule
- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.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 been made and 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 substitutes 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 QMS in accordance with Article 10(9) MDR is in place.
- Device(s) as listed in the attached schedule
- The device(s) continue to comply with the AIMDD or 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:

Medical Wire & Equipment Co (Bath) Ltd

Corsham,Wiltshire UK  31.05.2024

Amanda Nash, QA/RA Manager

Anash@mwe.co.uk

Schedule of Devices

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

| **Identification of the device(s)**[1] (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) |
|---|---|---|---|---|---|---|
| Transwab | GB20/965308 | 24/05/2024 | SGS Belgium NV NB1639 | SGS Belgium NV NB1639 | 31/12/2028 | |
| Sigma Transwab | GB20/965308 | 24/05/2024 | SGS Belgium NV NB1639 | SGS Belgium NV NB1639 | 31/12/2028 | |
| Dryswab | GB20/965308 | 24/05/2024 | SGS Belgium NV NB1639 | SGS Belgium NV NB1639 | 31/12/2028 | |
| Sigma GBS | GB20/965308 | 24/05/2024 | SGS Belgium NV NB1639 | SGS Belgium NV NB1639 | 31/12/2028 | |
| Sigma TSB | GB20/965308 | 24/05/2024 | SGS Belgium NV NB1639 | SGS Belgium NV NB1639 | 31/12/2028 | |
| Sigma Virocult | GB20/965308 | 24/05/2024 | SGS Belgium NV NB1639 | SGS Belgium NV NB1639 | 31/12/2028 | |
| Sigma VCM | GB20/965308 | 24/05/2024 | SGS Belgium NV NB1639 | SGS Belgium NV NB1639 | 31/12/2028 | |
| Fecal Transwab | GB20/965308 | 24/05/2024 | SGS Belgium NV NB1639 | SGS Belgium NV NB1639 | 31/12/2028 | |
| Amnicator | GB20/965308 | 24/05/2024 | SGS Belgium NV NB1639 | SGS Belgium NV NB1639 | 31/12/2028 | |