# 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*[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

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| Manufacturer name | Soteria Biotech Co., Ltd. |
| Manufacturer address and contact details | 12F, No.365 Fude 3rd Rd., Xizhi Dist.,<br>New Taipei City 22151<br>Taiwan |
| Single Registration Number (SRN) (if available) | TW-MF-000013120 |

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|---|---|
| Authorised Representative name (if applicable) | MT Promedt Consulting GmbH |
| Authorised Representative address and contact details | Ernst-Heckel-Straße 7<br>66386 St. Ingbert,<br>Germany |
| Single Registration Number (SRN) (if available) | DE-AR-000000085 |

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| Notified body name (if applicable) | TÜV SÜD Product Service GmbH<br>□ See attached schedule |
| Notified body number (if applicable) | CE0123<br>□ See attached schedule |
| Directive Certificate number(s)<br>to which this confirmation is made (if applicable) | G1 102623 0002 Rev. 00<br>□ See attached schedule |
| Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable) | 26 May 2024<br>□ See attached schedule |
| End date of extended validity/transition period | 31 December 2028<br>□ See attached schedule |

[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(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.

    Expired/expires *after* 20 March 2023:

    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 QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

- **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:**

Soteria Biotech Co., Ltd.

New Taipei City, Taiwan January 4, 2024

Hung Ta Hsiao, CEO

honda@soteriabio.com

[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) |
|---|---|---|---|---|---|---|
| **Soteria One Point Zero** | **G1 102623 0002 Rev. 00** | **26 May 2024** | **TÜV SÜD Product Service GmbH CE0123** | | **31 December 2028** | **N/A** |
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[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)