# Manufacturer's Declaration of Conformity

**for Class I non-sterile, non-measuring or Class 1 in vitro diagnostic (IVD) medical devices**

This Declaration of Conformity (DoC) is required under clause 6.6 (for single devices or kinds of devices) of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).
An Australian DoC must be completed by the manufacturer of a Class I non-sterile, non measuring device or a Class 1 in vitro diagnostic (IVD) device.

For more information on how to complete this DoC refer to Guidance for Declaration of Conformity for Class I non-sterile non-measuring and Class 1 in vitro diagnostic (IVD) medical devices.

This document can be:
- used for single or multiple devices.
- filled out by hand and then scanned and submitted or filled out electronically.

**Manufacturer's details**

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|---|---|
| Manufacturer's name | TERABio Tech Ltd |
| Manufacturer's business address | ELI LANDAU BLVD., 60, HERZLIYA, 685160, ISRAEL |

**Classification type**
Specify if your device is:
☒Class I non-sterile, non-measuring device
☒Class 1 in vitro diagnostic (IVD) medical device

**GMDN code and term**
Select the most appropriate Global Medical Device Nomenclature (GMDN) code for this product.
GMDN codes and terms are a system of internationally agreed generic descriptors that are used
to identify all medical device products. Class 1 IVDs require the use of a level 1 collective term (CT). Please refer to the following link for guidance regarding an appropriate CT for the kind of device: The use of GMDN codes for IVD medical devices in Australia.
GMDN codes are generated by the GMDN Agency.
The GMDN code tables are available on TGA Business Services (TBS).

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|---|---|
| GMDN codes 1. | BioSafety Station: Terahertz spectrometry breath analyser IVD, code: 65358 |

**Standards applied to the device(s)**
List any standards used in the manufacturing of the device, including:
- International Standards (ISO)
- Australian Standards (AS)
- Conformity Assessment Standard Orders (CASO)
- Medical Device Standard Orders (MDSO)

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|---|---|
| Standard | ISO 9001:2015<br>ISO 27001<br>EN ISO 14971<br>EN 13612<br>EN ISO 18113-1<br>EN 15223-1<br>EN 61010<br>EN 61326 (EMC in process) |

**Name of medical device(s) / IVD(s)**
Identify the specific device/s this form relates to for example, the name of the device or model numbers of the device and any variants that are being manufactured for supply in Australia.

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|---|---|
| Name of medical device(s)/IVD(s) | BioStation |

**This declaration is being made under clause 6.6 of Schedule 3 to the Regulations for a Class I non-sterile, non-measuring device or Class 1 IVD medical device.**
**By signing this form you are agreeing that:**

- You have reviewed the Declaration of Conformity procedures under Part 6 of Schedule 3 of the Regulations and the device complies with the applicable provisions of those procedures.
- The device complies with the relevant essential principles set out in Schedule 1 to the Regulations.
- The device complies with the applicable provisions of the classification rules set out in Schedule 2 to the Regulations.
- You will update the technical documentation when any changes are made in relation to the device.

**Important note**
Providing information that is false or misleading to a Commonwealth entity or in connection with a Commonwealth law is a serious offence subject to criminal penalties under the *Criminal Code Act 1995*.

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| Name | Eran Gabbai | | |
| Title | CTO | | |
| Signature |  | Date | June 13th 2021 |

TERABio Tech Ltd.
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