

# 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

|                                 |                                                                            |
|---------------------------------|----------------------------------------------------------------------------|
| Manufacturer's name             | Ningbo Baichen Medical Device Co., Ltd                                     |
| Manufacturer's business address | Room 2101, Diqu Building, 666 Taikang Middle Road, Ningbo, Zhejiang, China |

## 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 \(TBS\)](#).

|            |                                                                          |
|------------|--------------------------------------------------------------------------|
| GMDN codes | 40840- Wheelchair, attendant/occupant, electric drive/steer, collapsible |
|------------|--------------------------------------------------------------------------|

**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)

|           |      |
|-----------|------|
| Standards | s47G |
|-----------|------|

**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.

|                                  |      |
|----------------------------------|------|
| Name of medical device(s)/IVD(s) | s47G |
|----------------------------------|------|

**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*.

|           |     |      |            |
|-----------|-----|------|------------|
| Name      | s22 |      |            |
| Title     | s22 |      |            |
| Signature | s22 | Date | 2024-08-12 |