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	Sedana Medical Ltd
Manufacturer's business address	Unit 2A, The Village Centre, Two Mile House, Naas, Co. Kildare, W91 PWH5, Ireland.

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	34849

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	All applicable General Safety and Performance Requirements of Regulation (EU) 2017/745 EN ISO 13485:2016 EN ISO 14971:2019 ISO 20417:2021 ISO 5356-1:2015 ISO 15223-1:2021 IEC 62366-1:2015 ISO 2248:1985 EN ISO 12048:2001 ISO 19223:2019

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)	26094 – FlurAbsorb-S 26096 – FlurAbsorb

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	Lucinda Kelly		
Title	Regulatory Affairs & Quality Compliance Manager		
Signature		Date	25 Oct 2023