

Declaration of Conformity

- According to European Medical Device Directive 93/42/EEC -

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

Declares in its own responsibility that the products

Article number / Serial number: 1026100/1026050

<Anaesthetic Delivery System>

medical device classification Annex IX; Rule 2 and 3 of MDD 93/42/EEC

Class IIa

Conforms to:

- all applicable essential requirements of Annex I of MDD 93/42/EEC
- EN ISO 13485:2016
- EN ISO 14971:2019
- EN ISO 9360-1:2009
- EC 62366-1:2015
- IEC/TR 62366-2:2016

Following conformity assessment procedures, in accordance with:

Annex II of MDD 93/42/EEC

Certified by below Notified body:

BSI (NB number: 2797),

Dated: 05th March 2021

CE Certificate Number: CE 667826

Expiry Date: 26th April 2024

Signed:



Auindrila Das

PRRC, Person Responsible for Regulatory Compliance

Sedana Medical Ltd.

Naas, Co. Kildare, Ireland,

Date: 12 March 2021