

EC CERTIFICATION

EU QUALITY ASSURANCE CERTIFICATE

EU Regulation 2017/745 for Medical Devices, Annex XI Part A

We hereby declare that a conformity assessment based on a production quality assurance system restricted to the aspects of manufacture concerned with the conformity of the devices with sterility requirements - has been carried out following the requirements of EU Regulation 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Turon MedTech AB

Kardanvägen 21, SE- 432 32 Varberg, Sweden

Manufacturer SRN: SE-MF-000033162

Scope:

Sterility aspects of devices as detailed in attached product list.

Certificate Number:

28620168400

Revision:

00

Initial Certification Date:

26 February 2024

Date of Certification Decision:

26 February 2024

Certificate Issue Date:

26 February 2024

Certificate Expiry Date:

29 October 2028



Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.



PRODUCT LIST FOR CERTIFICATE

Issued to: Turon MedTech AB
Certificate number: 28620168400
Certificate valid from: 2024-02-26

Product List Issue Date:
26 February 2024

Product	Classification and EMDN	Intended use ¹	Date Added
Class I sterile devices			
<i>Basic UDI-DI: 7350131080403337F</i>			
40301 - Needle guide bushings (Ga 18)	Class I(s) A018002		2024-02-26
40302 - Needle guide bushings (Ga 20)	Class I(s) A018002		2024-02-26
40307 - Needle guide bushings (Ga 14)	Class I(s) A018002		2024-02-26
40308 - Needle guide bushings (Ga 16)	Class I(s) A018002		2024-02-26
40309 - Needle guide bushings (Ga 20 open)	Class I(s) A018002		2024-02-26
40311 - Needle guide bushings (Ga 22)	Class I(s) A018002		2024-02-26
40312 - Needle guide bushings (Ga 12)	Class I(s) A018002		2024-02-26



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¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

