

Annex to the EU Certificate no. 51268-60-01

valid from 2022-07-08 to 2025-02-18

Revision status of the annex: 1 dated 2022-11-11

Following devices/device categories are included in this certificate:

Class Ir

For the devices listed below, the review of the quality management system refers exclusively to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

Class	MDA/ MDN-Code	EMDN	Brand/ variants/ item code group
Ir	MDN 1208 MDS 1006	L 0312 Trocars	TrocaObt HASSON TrocaObt PYRAMID TrocaObt CONE TrocaObt SHIELD TrocaObt PROTECT EcoBalloon OBT RA(-S) EcoBalloon OBT DIL EcoBalloon OBT SB EcoBalloon OBT PROTECT(-S)
Ir	MDN 1208 MDS 1006	L 1203 Handpieces, mini-invasive surgery, reusable	EcoAx

Class IIa

Class	MDA/ MDN-Code	EMDN	Brand/ variants/ item code group
IIa	MDN 1201 MDS 1005	A010302 – Needles and kits – Plexus Block	SonoPlex® STIM SonoPlex® II SonoPlex® II NRFit® UniPlex® NanoLine® UniPlex® II NRFit® SonoBlock SonoBlock II SonoBlock II NRFit® PeriLong SPROTTE® PeriLong SPROTTE® NRFit® PeriLong NRFit® SonoTAP® SonoTAP® II SonoTAP® II NRFit® SonoLong NanoLine® SonoLong NanoLine® NRFit® PlexoLong NanoLine® PlexoLong NanoLine® NRFit® KombiPlex QInject PeriLong InFiltr SonoMSK
IIa	MDN 1201 MDS 1005	A0799 – Adapters, connectors, ramps, stopcocks, caps – other	ClampingAdapter ClampingAdapter NRFit®
IIa	MDN 1201 MDS 1005	A04010101 – Administration and collecting filters	Filter Filter NRFit®

Class	MDA/ MDN-Code	EMDN	Brand/ variants/ item code group
Ila	MDN 1201 MDS 1005	A020102 – Infusion and irrigation disposable syringes	Syringe Syringe NRFit®
Ila	MDN 1201 MDS 1005	A01010199 – Hypodermic needles – others	IntroDucer IntroDucer Sono IntroDucer 2.G IntroDucer NRFit® Coaxial sleeve Chiba Permanent cannulas TunnEler GCS SPROTTE® Injection cannula Injection cannula NRFit® Initial cannula Special puncture canula acc. SPROTTE® PTC
Ila	MDN 1201 MDS 1005	C01010199 – I.V. cannulas – others	VascularSono
Ila	MDN 1201 MDS 1005	A010599 – Ophthalmology injection needles and kits – other	SonoEye
Ila	MDN 1201 MDS 1005	A01020299 – Needles and kits – bone marrow biopsy – other	TrokaBone TrokaCut
Ila	MDN 1201 MDS 1005	A01020101 – Shearing biopsy needles	DeltaCut Biopsy
Ila	MDN 1201 MDS 1005	A019012 – Needles and systems breast nodes location (and other sites)	MammaLoc Sono Mammography localization set
Ila	MDN 1201 MDS 1005	A01020102 – Aspiration fine needles and kits	Chiba Chiba Sono
Ila	MDN 1201 MDS 1005	K01020101 – Endotherapy, dissectors, single-use	EcoBalloon DIL, DIL-XL, DIL-BI MonoBalloon DIL, DIL-XL, DIL-BI
Ila	MDN 1201 MDS 1005	K01020199 – Endotherapy, single-use surgical instrumentary – others	EcoBalloon SL, SL-S, RA, RA-S, URO-URO-S, SB MonoBalloon SL, SL-S, RA, RA-S, URO-URO-S, SB VarioBalloon SL, SL-S, RA, RA-S, URO-URO-S, SB VarioBalloon Duo MonoBalloon Duo EcoBalloon Duo

Class III

MDN1201 (Non-active non-implantable devices for anaesthesia, emergency and intensive care)

- Quincke cannulas for lumbar puncture (LUER, NRFit®), Basic-UDI-DI: 4048223-R20-1060CU, 4048223-R20-1066D8
- CauDal (LUER/ NRFit®) Cannula/ Needle, Basic-UDI-DI: 4048223-R20-0070CQ, 4048223-R20-0071CS, 4048223-R20-0072CU
- SPROTTE® SPECIAL Cannula, Basic-UDI-DI: 4048223-R20-0035CN
- SPROTTE® STANDARD (LUER/ NRFit®) Anaesthesia: Cannula/ Needle, Basic-UDI-DI: 4048223-R20-0001C5, 4048223-R20-0003C9, 4048223-R20-0004CB, 4048223-R20-0005CD, 4048223-R20-0006CF, 4048223-R20-0012CA, 4048223-R20-0014CE, 4048223-R20-0015CG, 4048223-R20-0016CJ, 4048223-R20-0024CH, 4048223-R20-0025CK, 4048223-R20-0027CP, 4048223-R20-0033CJ, 4048223-R20-0034CL, 4048223-R20-0037CS
- Tuohy (LUER/ NRFit®) Cannula/ Needle, Basic-UDI-DI: 4048223-R20-0055CU, 4048223-R20-0056CW, 4048223-R20-0060CM, 4048223-R20-0061CP, 4048223-R20-0062CR
- EpiLong Cath / IntraLong Cath (LUER/ NRFit®) Catheters CNS (central nervous system), Basic-UDI-DI: 4048223-R20-0220CK, 4048223-R20-0225CV, 4048223-R20-0228D3, 4048223-R20-0245D3, 4048223-R20-0246D5
- SPROTTE® STANDARD (LUER/ NRFit®) Lumbar puncture, Basic-UDI-DI: 4048223-R20-1024CQ, 4048223-R20-1025CS, 4048223-R20-1026CU, 4048223-R20-1027CW, 4048223-R20-1048D6, 4048223-R20-1050CR
- Disposable Biopsy Needle, Basic-UDI-DI: 4048223-R20-1103CM
- Biopsy Needle System BrainPro / Biopsy Needle System in Disposable Biopsy Needle Sedan, Basic-UDI-DI: 4048223-R20-1100CF / 4048223-R20-1102CF

For the initial placing on the market of class III devices covered by this certificate, an EC EU technical documentation assessment certificate according to Regulation (EU) 2017/745 Annex IX Chapter II is required.



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