

Doc Number	CE-01-B	
Revision	1.0	Effective: 2022/02/10
Doc Type	Registration Dossier (Confidential)	

EC Declaration of Conformity

Manufacturer:

GENMED ENTERPRISES INTERNATIONAL LTD
Fountain House, Fountain Lane, St Mellons,
Cardiff, United Kingdom CF3 0FB
SRN: GB-MF-000010687

Authorized Representative

Genmed Enterprises Medical Ltd
30 Botanic Avenue, Drumcondra, Dublin,
Ireland D09 CF85
SRN: IE-AR-000010419

We, the manufacturer, herewith declare that the products

Sterile Trocars for Single Use
Type: refer to the attachment
Basic UDI-DI code:[506091140TROCARA4]

meet the provisions of the Regulation (EU) 2017/745 and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

The medical device has been assigned to *class Ila, rule 7*, according to Annex VIII of Regulation (EU) 2017/745. It bears the mark



Conformity assessment procedure: Annex II + III & Annex XI Part A.

Standards applied: Applied standards are listed in the GSPR checklist of the CE technical file

Intended use: it is intended used in endoscopic procedures to provide a port of entry for endoscopic instruments.

Compliance of the designated product with the Regulation (EU) 2017/745 has been assessed by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: DZ 2318749-1
Issue date: 2022-02-09
Expiry date: 2027-01-20

following the conformity assessment procedure specified above.

This Declaration of conformity is valid in connection with the released document for the respective batch of produced devices

The above mentioned declaration of conformity is under the sole responsibility of

GENMED ENTERPRISES INTERNATIONAL LTD

Cardiff, 2022-02-10

Place, date



Legally binding signature, Function



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Attachment:

Product Scope / Models

Name Of Medical Device			Sterile trocars for single use	
Proposed Grouping For Medical Device			:Non-active device	
Medical Device code			MDN 1208 Non-active non-implantable instruments	
Generic Device Group (ENMD code on level 4)			K010101,	
Product name (using nomenclature of basic UDI-DI)			ENDOTHERAPY TROCARS, SINGLE-USE	
Basic UDI-DI code			506091140TROCARA4	
Name As Per Device Label		Identifier (UDI-DI)	Genmed code	Brief Description of Item
Sterile trocars for single use (Bladeless basic type)		5060911400004	GN-TW1510	Disposable Bladeless trocar, R:15mm L:100mm
		5060911400011	GN-TW1210	Disposable Bladeless trocar, R:12mm L:100mm
		5060911400028	GN-TW1275	Disposable Bladeless trocar, R:12mm L:75mm
		5060911400035	GN-TW1010	Disposable Bladeless trocar, R:10mm L:100mm
		5060911400042	GN-TW0575	Disposable Bladeless trocar, R:5mm L:75mm
		5060911400059	GN-TW0510	Disposable Bladeless trocar, R:5mm L:100mm
Sterile trocars for single use (Bladeless basic type) Dual pack		5060911400066	GN-TW1075	Disposable Bladeless trocar, R:10mm L:75mm
		5060911400073	GN-TW0515	Disposable Bladeless trocar, R:5mm L:150mm
		5060911400080	GN-TW1210-D	Disposable Bladeless trocar plus extra cannula, R:12mm L:100mm
		5060911400097	GN-TW1010-D	Disposable Bladeless trocar plus extra cannula, R:10mm L:100mm
		5060911400103	GN-TW0575-D	Disposable Bladeless trocar plus extra cannula R:5mm L:75mm
		5060911400110	GN-TW0510-D	Disposable Bladeless trocar plus extra cannula R:5mm L:100mm
Sterile OBTURATOR for single use (Bladeless normal type)		5060911400127	GN-TW1210-O	Disposable Obturator Bladeless R:12mm L:100mm
		5060911400134	GN-TW1275-O	Disposable Obturator Bladeless R:12mm L:75mm
		5060911400141	GN-TW1075-O	Disposable Obturator Bladeless R:10mm L:75mm
		5060911400158	GN-TW1010-O	Disposable Obturator Bladeless R:10mm L:100mm
		5060911400165	GN-TW0575-O	Disposable Obturator Bladeless R:5mm L:75mm
		5060911400172	GN-TW0510-O	Disposable Obturator BladelessR:5mm L:100mm
Sterile trocars for single use (Optical basic type)		5060911400189	GN-TO1510	Disposable Optical trocar, R:15mm L:100mm
		5060911400196	GN-TO1215	Disposable Optical trocar, R:12mm L:150mm



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	5060911400202	GN-TO1210	Disposable Optical trocar, R:12mm L:100mm
	5060911400219	GN-TO1275	Disposable Optical trocar, R:12mm L:75mm
	5060911400226	GN-TO1075	Disposable Optical trocar, R:10mm L:75mm
	5060911400233	GN-TO1010	Disposable Optical trocar, R:10mm L:100mm
	5060911400240	GN-TO0575	Disposable Optical trocar, R:5mm L:75mm
	5060911400257	GN-TO0510	Disposable Optical trocar, R:5mm L:100mm
	5060911400264	GN-TO0515	Disposable Optical trocar, R:5mm L:150mm
	5060911400271	GN-TO1510-O	Disposable Optical ObturatorR:15mm L:100mm
	5060911400288	GN-TO1215-O	Disposable Optical ObturatorR:12mm L:150mm
	5060911400295	GN-TO1210-O	Disposable Optical ObturatorR:12mm L:100mm
Sterile OBTURATOR for single use (Optical normal type)	5060911400301	GN-TO1010-O	Disposable Optical ObturatorR:10mm L:100mm
	5060911400318	GN-TO0575-O	Disposable Optical ObturatorR:5mm L:75mm
	5060911400325	GN-TO0510-O	Disposable Optical ObturatorR:5mm L:100mm
	5060911400332	GN-TO1215-D	Disposable Optical trocar plus extra cannula, R:12mm L:150mm
	5060911400349	GN-TO1210-D	Disposable Optical trocar plus extra cannula, R:12mm L:100mm
	5060911400356	GN-TO1275-D	Disposable Optical trocar plus extra cannula, R:12mm L:75mm
	5060911400363	GN-TO1010-D	Disposable Optical trocar plus extra cannula, R:10mm L:100mm
	5060911400370	GN-TO1075-D	Disposable Optical trocar plus extra cannula, R:10mm L:75mm
	5060911400387	GN-TO0575-D	Disposable Optical trocar plus extra cannula, R:5mm L:75mm
	5060911400394	GN-TO0510-D	Disposable Optical trocar plus extra cannula, R:5mm L:100mm
Sterile trocars for single use (Optical basic type) Dual pack	5060911400400	GN-TO0515-D	Disposable Optical trocar plus extra cannula, R:5mm L:150mm
	5060911400417	GN-T1510-C	Disposable Universal cannulaR:15mm L:100mm
	5060911400424	GN-T1215-C	Disposable Universal cannulaR:12mm L:150mm
	5060911400431	GN-T1210-C	Disposable Universal cannulaR:12mm L:100mm
	5060911400448	GN-T1275-C	Disposable Universal cannulaR:12mm L:75mm
	5060911400455	GN-T1010-C	Disposable Universal cannulaR:10mm L:100mm
	5060911400462	GN-T1075-C	Disposable Universal cannulaR:10mm L:75mm
	5060911400479	GN-T0575-C	Disposable Universal cannulaR:5mm L:75mm
	5060911400486	GN-T0510-C	Disposable Universal cannulaR:5mm L:100mm
Sterile trocars for single use (Universal cannula basic type)			



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Sterile trocars for single use (Cannula Balloon ring fixation type)	5060911400493	GN-T0515-C	Disposable Universal cannula R:5mm L:150mm
	5060911400509	GN-TF1210-C	Disposable Cannula balloon ring fixation trocar, R:12mm L:100mm
	5060911400516	GN-TF1010-C	Disposable Cannula balloon ring fixation trocar, R:10mm L:100mm
	5060911400523	GN-TF0575-C	Disposable Cannula balloon ring fixation trocar, R:5mm L:75mm
	5060911400530	GN-TF0510-C	Disposable Cannula balloon ring fixation trocar, R:5mm L:100mm
Sterile trocars for single use (Optical Bladeless Balloon ring fixation type) Dual pack	5060911400547	GN-TOF1210-D	Disposable Optical balloon ring fixation trocar plus extra cannula R:12mm
	5060911400554	GN-TOF1010-D	Disposable Optical balloon ring fixation trocar plus extra cannula R:10mm
	5060911400561	GN-TOF0575-D	Disposable Optical balloon ring fixation trocar plus extra cannula R:5mm
	5060911400578	GN-TOF0510-D	Disposable Optical balloon ring fixation trocar plus extra cannula R:5mm
	5060911400585	GN-TBF1210-D	Disposable Bladed balloon ring fixation trocar plus extra cannula R:12mm
Sterile trocars for single use (Bladed Balloon ring fixation type) Dual pack	5060911400592	GN-TBF1010-D	Disposable Bladed balloon ring fixation trocar plus extra cannula R:10mm
	5060911400608	GN-TBF0575-D	Disposable Bladed balloon ring fixation trocar plus extra cannula R:5mm
	5060911400615	GN-TBF0510-D	Disposable Bladed balloon ring fixation trocar plus extra cannula R:5mm
	5060911400622	GN-TBF1210	Disposable bladed balloon ring fixation trocar, R:12mm L:100mm
	5060911400639	GN-TBF1010	Disposable bladed balloon ring fixation trocar, R:10mm L:100mm
Sterile trocars for single use (Bladed FIXATION balloon type)	5060911400646	GN-TBF0575	Disposable bladed balloon ring fixation trocar, R:5mm L:75mm
	5060911400653	GN-TBF0510	Disposable bladed balloon ring fixation trocar, R:5mm L:100mm
	5060911400660	GN-TOF1210	Disposable Optical balloon ring fixation trocar, R:12mm L:100mm
	5060911400677	GN-TOF1010	Disposable Optical balloon ring fixation trocar, R:10mm L:100mm
	5060911400684	GN-TOF0575	Disposable Optical balloon ring fixation trocar, R:5mm L:75mm
Sterile trocars for single use (Optical FIXATION balloon type)	5060911400691	GN-TOF0510	Disposable Optical balloon ring fixation trocar, R:5mm L:100mm
	5060911400707	GN-TOF0515	Disposable Optical balloon ring fixation trocar, R:5mm L:150mm
	5060911400714	GN-TWF1210	Disposable Bladeless balloon ring fixation trocar, R:12mm L:100mm
	5060911400721	GN-TWF1010	Disposable Bladeless balloon ring fixation trocar, R:10mm L:100mm
	5060911400738	GN-TWF0575	Disposable Bladeless balloon ring fixation trocar, R:5mm L:75mm
Sterile trocars for single use (Bladeless FIXATION balloon type)	5060911400745	GN-TWF0510	Disposable Bladeless balloon ring fixation trocar, R:5mm L:100mm
	5060911400752	GN-TWF0515	Disposable Bladeless balloon ring fixation trocar, R:5mm L:150mm
	5060911400769	GN-TWF1210-D	Disposable Bladeless balloon ring fixation trocar, R:12mm L:100mm
	5060911400776	GN-TWF1010-D	Disposable Bladeless balloon ring fixation trocar, R:10mm L:100mm
			Disposable Bladeless balloon ring fixation trocar, R:5mm L:75mm



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	5060911400783	GN-TWF0575-D	Disposable Bladeless balloon ring fixation trocar plus extra cannulaR:5mm
	5060911400790	GN-TWF0510-D	Disposable Bladeless balloon ring fixation trocar plus extra cannulaR:5mm
Sterile trocars for single use(bladed normal type)	5060911400806	GN-TB1210	Disposable bladed trocar, bladedR:12mm L:100mm
	5060911400813	GN-TB1010	Disposable bladed trocar, bladedR:10mm L:100mm
	5060911400820	GN-TB0575	Disposable bladed trocar, bladedR:5mm L:75mm
	5060911400837	GN-TB0510	Disposable bladed trocar, bladedR:5mm L:100mm
Sterile OBTURATOR for single use (bladed normal type)	5060911400844	GN-TB1210-O	Disposable bladed ObturatorR:12mm L:100mm
	5060911400851	GN-TB1010-O	Disposable bladed ObturatorR:10mm L:100mm
	5060911400868	GN-TB0575-O	Disposable bladed ObturatorR:5mm L:75mm
	5060911400875	GN-TB0510-O	Disposable bladed ObturatorR:5mm L:100mm
Sterile trocars for single use(bladed normal type) Dual pack	5060911400882	GN-TB1210-D	Disposable bladed trocar plus extra cannulaR:12mm L:100mm
	5060911400899	GN-TB1010-D	Disposable bladed trocar plus extra cannulaR:10mm L:100mm
	5060911400905	GN-TB0575-D	Disposable bladed trocar plus extra cannulaR:5mm L:75mm
	5060911400912	GN-TB0510-D	Disposable bladed trocar plus extra cannula, R:5mm L:100mm
Sterile trocars for single use (Hassan anchor fixation balloon type)	5060911400929	GN-TOHF1210	Disposable Hassan balloon trocar blunt obturator, with balloon/anchor
	5060911400936	GN-TOHF1010	Disposable Hassan balloon trocar blunt obturator, with balloon/anchor
	5060911400943	GN-TOHF0510	Disposable Hassan balloon trocar blunt obturator, with balloon/anchor
Sterile trocars for single use (Hassan anchor basic type) No balloon	5060911400950	GN-TH1210	Disposable Hassan trocar blunt obturator with anchor fixation, R:12mm
	5060911400967	GN-TH1010	Disposable Hassan trocar blunt obturator with anchor fixation, R:10mm
	5060911400974	GN-TH0510	Disposable Hassan trocar blunt obturator with anchor fixation, R:5mm
Visi-mate	5060911401254	GN-VIS01	Device for fixing the endoscope of Optical trocar
	5060911401261	GN-VIS02	Device for fixing the endoscope of Optical trocar
	5060911401278	GN-VIS03	Device for fixing the endoscope of Optical trocar

Trocar Kits
<p>Above mentioned product could be packaged in vary combination in different Kits.</p> <p>The Kits could also include disposable veress needle and disposable sample retrieval bags as optional.</p> <p>All items included in the kits are CE certified individually.</p>

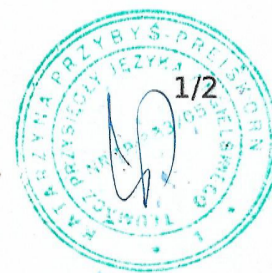


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Cardiff, 2022-02-10
Place , date


Legally binding signature, Function

mgr Katarzyna Przybyś-Preiskorn
Tłumaczka przysięgła języka angielskiego
przy Ministerstwie Sprawiedliwości
Nr TP/883/05
05-410 Józefów, Spacerowa 43b
tel/fax (+22) 789 29 37
[tłumaczenie z jęz. angielskiego]



*[stopka każdej ze stron zawiera nazwę firmy Genmed Enterprises International Ltd.,
informację POUFNE oraz numer strony]*

[logo Genmed]

Numer dokumentu CE-01-B
Wersja 1.0 Obowiązuje: 2022/02/10
Typ dokumentu Dokumentacja rejestracyjna (poufna)

Deklaracja zgodności WE

Producent:
GENMED ENTERPRISES INTERNATIONAL LTD
Fountain House, Fountain Lane, St Mellons,
Cardiff, Wielka Brytania CF3 0FB
SRN: GB-MF-000010687

Autoryzowany przedstawiciel:
Genmed Enterprises Medical Ltd
30 Botanic Avenue, Drumcondra, Dublin,
Irlandia D09 CF85
SRN: IE-AR-000010419

Jako producent, niniejszym oświadczamy, że wyroby

Sterylny trokary jednorazowego użytku

Typ: patrz załącznik

Podstawowy kod UDI-DI:[506091140TROCARA4]

spełniają przepisy rozporządzenia (UE) 2017/745 i jego transpozycji do prawa krajowego, które mają do nich zastosowanie. Deklaracja jest ważna w połączeniu z "końcowym sprawozdaniem z kontroli" wyrobu.



Wyrób medyczny został przypisany do **klasy IIa, reguła 7**, zgodnie z załącznikiem VIII do rozporządzenia (UE) 2017/745. Jest on opatrzony znakiem

CE 0197

Procedura oceny zgodności: Załącznik II + III i załącznik XI część A.
Zastosowane normy: Zastosowane normy są wymienione na liście kontrolnej GSPR w dokumentacji technicznej CE.
Przeznaczenie: jest przeznaczony do stosowania w procedurach endoskopowych w celu zapewnienia portu wejścia dla instrumentów endoskopowych.

Zgodność wyznaczonego wyrobu z Rozporządzeniem (UE) 2017/745 została oceniona przez Jednostkę Notyfikowaną

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Niemcy

Certyfikat nr: DZ 2318749-1

Data wydania: 2022-02-09

Data ważności: 2027-01-20

zgodnie z procedurą oceny zgodności określoną powyżej.

Niniejsza deklaracja zgodności jest ważna w połączeniu z dokumentem wydanym dla danej partii wyprodukowanych wyrobów.

Wyłącznie odpowiedzialność za powyższą deklarację zgodności ponosi

GENMED ENTERPRISES INTERNATIONAL LTD

Cardiff, 2022-02-10

Miejsce, data

[podpis odręczny nieczytelny]

Prawnie wiążący podpis, funkcja

[ciąg dalszy dokumentu stanowiący załącznik nie został przetłumaczony]



POŚWIADCZAM, ŻE POWYŻSZE TŁUMACZENIE JEST
ZGODNE Z PRZEDSTAWIONYM MOCNYM DOKUMENTU

mgr KATARZYNA PRZYBYŚ-PRISKORN

TŁUMACZ PRZYSIĘGŁY JĘZYKA ANGIELSKIEGO

JÓZEFÓW, DN. 12.06.2022 Nr REPERTORIUM 2021.06/25