



SIQ Ljubljana

Mašera-Spasićeva ulica 10

SI-1000 Ljubljana

Slovenija

T +386 1 4778 100

F +386 1 4778 444

info@siq.si, www.siq.si

vaš znak / your ref.:

OSV/3647

naš znak / our ref.:

2025-02-25

datum / date:

SGM d.o.o.
Grge Novaka 22/A

21000 SPLIT
Croatia

Subject: Statement on the non-significant change regarding transitional provision under Article 120 of the MDR and additional notice to the certificate MDD-153

SIQ Ljubljana (NB 1304) hereby confirms that the

SGM d.o.o.
Grge Novaka 22/A

21000 SPLIT
Croatia

informed SIQ Ljubljana about the additional variant of twisted pair needle electrode from the scope of the CE certificate and the organization's products.

The organization provided all necessary documentation regarding the change.

SIQ Ljubljana (NB 1304) conducted the review of documentation and hereby confirms that the organization's change is non-significant.

SIQ Ljubljana as a certification and Notified body regularly checks whether an EC certificate holder meets the requirements of the Medical Device Directive 93/42/EEC by surveillance audits at least once a year.

On the basis of the organization's Notice of Change dated 2025-01-09 and submitted documentation, SIQ Ljubljana hereby issues an Additional notice to the Detailed list of product names, models, and types annexed to the certificate MDD-153, version 02, issued on 2021-05-12 (valid until 2024-05-26, however transition timeline applies in line with Article 120.3c of MDR (as amended by (EU) 2023/607), as stated in Confirmation letter 3647-2024/01, dated 2024-05-20):

Detailed list of product names, models and types:

Certificate No.: **MDD-153**
Issued to: SGM d.o.o.,
Grge Novaka 22A, 21000 Split, Croatia
Place of production: SGM d.o.o.,
Grge Novaka 22A, 21000 Split, Croatia
Product category: Disposable sterile neurological electrodes
GMDN: 47714
Classification: IIa
Product name: CS

Alternative name: Disposable sterile corkscrew electrode
 Model/Type: See code breakdown below
 Product name: N
 Alternative name: Disposable sterile needle electrode
 Model/Type: See code breakdown below
 Product name: TPN, TTN
 Alternative name: Disposable sterile needle electrode
 Model/Type: See code breakdown below
 Product name: HW, PHW
 Alternative name: Disposable hookwire electrode
 Model/Type: See code breakdown below

Code Breakdown:

OBJAŠNJENJE SUSTAVA KODIRANJA
 PN-NL-WL-QN-CN

PN – Vrsta, podgrupa proizvoda

CS – Corkscrew
 N – Single Needle Electrode
 TPN or TTN – Twisted Pair needle elektrode
 HW – Hook wire elektrode
 PHW – Paired Hook Wire elektrode

NL – Duljina igle (7-25 mm)

Značajka po kojoj se temeljno razlikuju proizvode:
 Kod CS – igle to je 15
 Kod N i TPN igala raspon je od 7-25 mm
 Kod HW Elektroda to ovisi o duljini HYPODERMIC igle.
 Trenutno dostupne verzije s: 13, 19, 15, 30, 50 i 85 mm

WL – Duljina vodiča. (0,1-3,0 m)

Za proizvode iz grupa CS, N, TPN je u dm jedinici pa je duljina od 1,5 . napisana kao 15.
 Za Hookwire je u CM, pa je tipična duljina od 40 cm napisana kao 40.

QN – broj elektroda u pakiranju (01-24)

CN – broj različitih boja u pakiranju (1-12)

Opisuje broj boja u pakiranju. Obzirom da proizvod: iste duljine igle i dužine vodiča može biti drukčije pakiran.

Napomena:

Kod HW i PHW elektrode je to informacije jeli kraj žice:
 TERMINIRAN - 11
 OGOLJEN – 00

CS - ELEKTRODE

ITEM No.	Needle	Calibre	Lead Wire	wire color	Packaging	NEW PRODUCT NUM
003-400000-24	15mm	0.6mm (23G)	1.0m	6	carton box/24	CS-15-10-24-C6
003-400000-06	15mm	0.6mm (23G)	1.0m	6	Pouch/06	CS-15-10-06-C6
003-400001-24	15mm	0.6mm (23G)	1.5m	6	carton box/24	CS-15-15-24-C6
003-400001-06	15mm	0.6mm (23G)	1.5m	6	Pouch/06	CS-15-15-06-C6
003-400001-4	15mm	0.6mm (23G)	2.0m	4	Pouch/1	CS-15-20-04-C4
003-400001-5	15mm	0.6mm (23G)	2.0m	5	Pouch/1	CS-15-20-05-C5

N - ELEKTRODE

ITEM No.	Needle	Calibre	Lead Wire	wire color	Packaging	NEW PRODUCT NUM
003-400101-24	12mm	0.35mm (28G)	1.5m	6	carton box/24	N-12-15-24-C6
003-400101-24	12mm	0.35mm (28G)	1.5m	12	carton box/24	N-12-15-24-C12
003-400101-06	12mm	0.35mm (28G)	1.5m	6	Pouch/06	N-12-15-06-C6
003-400106-24	18mm	0.35mm (28G)	1.5m	6	carton box/24	N-18-15-24-C6
003-400106-06	18mm	0.35mm (28G)	1.5m	6	Pouch/06	N-18-15-06-C6
003-400107-24	7mm	0.35mm (28G)	1.5m	6	carton box/24	N-07-15-24-C6
003-400107-06	7mm	0.35mm (28G)	1.5m	6	Pouch/06	N-07-15-06-C6

TPN - ELEKTRODE

ITEM No.	Needle	Calibre	Lead Wire	wire color	Packaging	NEW PRODUCT NUM
003-400121-12	12mm	0.35mm (28G)	2.0 m	8	carton box/12	TPN-12-20-12-C8
003-400121-03	12mm	0.35mm (28G)	2.0 m	4	Pouch/03	TPN -12-20-03-C4
003-400124-03	12mm	0.35mm (28G)	2.0 m	6	Pouch/03	TPN -12-20-03-C6
003-400123-12	12mm	0.35mm (28G)	2.5m	8	carton box/12	TPN -12-25-12-C8
003-400126-12	12mm	0.35mm (28G)	1.5 m	8	carton box/12	TPN -12-15-12-C8
003-400122-12	18mm	0.35mm (28G)	2.0 m	8	carton box/12	TPN -18-20-12-C8
003-400122-03	18mm	0.35mm (28G)	2.0 m	4	carton box/12	TPN -18-20-03-C4
003-400125-03	18mm	0.35mm (28G)	2.0 m	6	Pouch/06	TPN -18-20-03-C6
003-400127-12	7mm	0.35mm (28G)	2.0 m	8	carton box/24	TPN -07-20-12-C8
003-400127-03	7mm	0.35mm (28G)	2.0 m	4	Pouch/03	TPN -07-20-03-C4
003-400132-10	18mm	0.35mm (28G)	1.5 m	3	carton box/10	TTN -18-15-10-C3

HW i PHW - ELEKTRODE

ITEM No.	Wire Length	Needle length	Calibre	TERMINATION	Packaging	NEW PRODUCT NUM
003-400160-24	0,4 m	13mm	0,45mm (26G)	DA	carton box/24	HW-13-40-24-11
003-400160-06	0,4 m	13mm	0,45mm (26G)	DA	Pouch/06	HW-13-40-06-11
003-400166-24	0,15	19mm	0,4mm (26G)	DA	carton box/24	HW-19-10-24-11
003-400167-24	0,15	25mm	0,5mm (25G)	DA	carton box/24	HW-25-15-24-11
003-400162-06	0,4 m	50mm	0,7mm (22G)	DA	Pouch/06	PHW-50-40-06-11
003-400162-03	0,4 m	50mm	0,6mm (23G)	NE	Pouch/03	PHW-50-40-03-00
003-400163-06	0,4 m	30mm	0,6mm (23G)	DA	Pouch/06	PHW-30-40-06-11
003-400163-05	0,4 m	30mm	0,6mm (23G)	DA	Pouch/05	PHW-30-40-05-11
003-400163-03	0,4 m	30mm	0,6mm (23G)	NE	Pouch/03	PHW-30-40-03-00
003-400169-06	0,4 m	80	0,6mm (23G)	DA	Pouch/06	PHW-80-40-06-11
003-400169-06	0,4 m	80	0,6mm (23G)	NE	Pouch/06	PHW-80-40-06-00
003-400169-03	0,4 m	80	0,6mm (23G)	NE	Pouch/03	PHW-80-40-03-00

For any further information, we are available by phone at 00 386 1 4778 106 and by email at maja.kramar@siq.si.

Management Systems Assessment
MDD Product Manager
Ana Pribaković Borštnik

za Kga Tyle