Device Master Record

18.03.2022

Reference Number: **1894/12.5**
Internal Number: **3002**

GENERAL INFORMATION

Description:	Haemostatic forceps
Intendend Use:	An artery clamp, also referred to as vessel clamp, is a medical instrument used to grasp and hold severed blood vessels for short periods, for primary haemostasis or before intended ligation, for example during an operation.
Use conditions:	In medical and preventive treatment facility

FACILITIES

Manufacturer:	Carl Martin GmbH Neuenkamper Straße 80-86 42657 Solingen Germany
Design facility:	Carl Martin GmbH Neuenkamper Straße 80-86 42657 Solingen Germany

MEDICAL DEVICE INFORMATION

Risk classification:	1r
Risk classification rule:	6
Basic UDI Group No:	85
Basic UDI Group Desc:	Arterienklemme / Blutstillungsmeißel
Basic UDI:	++ECMSBUDI0857L
UDI-DI:	+ECMS30021/$U
Components:	-
Accessoires:	-
Device compatibility:	-
Biocompatibility:	Tested for cytotoxicity according to EN ISO 10993-5:2009

DIMENSIONS

Device Width:	8,5 mm
Device Height:	2 mm
Device Length:	17 mm
Device Weight:	0,021 kg

PACKAGING

Package Length:	17 cm
Package Width:	8,5 cm
Package Weight:	0,011 kg

Warnings: Intended for use by dental professionals only. Must be checked for fault-free operation (fractures, cracks, malfunctions, etc.) and be cleaned, disinfected and sterilized before each use. New instruments are contaminated with oils and fats from the manufacturing process and must therefore be cleaned thoroughly before the first sterilisation with a suitable cleaning agent. For more information please visit: www.carlmartin.de

Shelf Life: The product is sold in non sterile packaging. Shelf life is not applicable.

Package Information: The package is labeled with the device identifying label. This label contains the following information for each instrument.

- Reference Number

- Batch code


- Name and address of the manufacturer


- CE-mark

- Non-sterile

- Medical Device


- Follow the IFU


- Temperature limitation


- UDI-DI DataMatrix Code

OTHERS

Dispose: In accordance with accepted medical practise and applicable local, state, and federal laws and regulations.

Reprocessing:	In accordance with the work instruction for reprocessing 'QSA313'.
Steilization:	In accordance with the work instruction for reprocessing 'QSA313'.
Reprocessing limits	Frequent reprocessing has little effect on these instruments. The end of the product's service life is normally determined by the wear and damage during use.

PRODUCT MARKING

Marking includes:
1. CE-Symbol acc. to Annex V, 2017/745 MDR
2. Carl Martin brand logo
3. Reference number
4. 'LOT' symbol acc. to ISO 15223-1 with batch number
5. 'Medical Device' symbol acc. to ISO 15223-1

Comment: Normally, each symbol or information above is marked on every instrument. If there is technically not enough space to mark all of these information, some of them will not be marked. Prioritized in descending order according to the list above.

REGULATORY AFFAIRS

Warranty: The responsibility for the proper cleaning, disinfection and sterilisation of instruments lies with the user. It is essential to observe national regulations. Carl Martin GmbH excludes any warranty claims and shall not be liable for indirect damages or subsequent damages arising from:
- misappropriate use, application or handling
- improper processing and sterilisation
- improper use, application or handling
- improper repairs
- non-compliance with this Work Instruction
- Individual parts may not be replaced with parts from other manufacturers

Regulatory requirements:
- Medical Device Regulation 2017/745 (European Union)
- Medical Device Directivy 93/42/EEC (European Union)
- Medizinprodukterecht (Germany)
- DIN EN ISO 7153-1 (standard)
- DIN EN ISO 10993 (standard)
- DIN EN ISO 13485 (standard)
- DIN EN ISO 14971 (standard)
- DIN EN ISO 15223-1 (standard)
- DIN EN ISO 15883-1 (standard)
- DIN EN ISO 17664 (standard)
- DIN EN ISO 19011 (standard)
- DIN EN 13060 (standard)
- EN ISO 11607-1 (standard)
- EN ISO 11737-1 (standard)
- EN ISO 11737-2 (standard)
- EN 285 (standard)
- EN 867-5 (standard)