ME Medical

PRODUCT DATA SHEET

PROFESSIONAL CLIPPER

Document: QM-008

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1. Composition of the product:

   The body of the surgical clipper body and charging station is made of non-toxic ABS (acryl-butadiene-styrene copolymer). The blade is made of 420j2.

   It is equipped with a re-chargeable Li-ion battery

   This product data sheet covers the following items:

   REF SC004 ME Medical™ Professional Clipper (with charging station)
   REF SC002 UNIVERSAL Single-use blade to Model SC001/SC004
   REF SC003 NEURO Single-use blade to Model SC001/SC004

2. Packaging, structure and composition

Unit container

- a corrugated cardboard box (cellulose) with self-adhesive label. PVC tray.
- inner box dimensions: REF SC004: 153 x 82 x 193 mm
  REF SC002: 135 x 53 x 345 mm
  REF SC003: 267 x 67 x 75 mm

Transport container (outer box)

- a corrugated cardboard carton (cellulose) with self-adhesive label
- outer box dimensions: REF SC004: 480 x 350 x 220 mm = 0.037 CBM
  REF SC002: 355 x 282 x 179 mm = 0.018 CBM
  REF SC003: 279 x 243 x 168 mm = 0.012 CBM
- Gross/net weight: (outer box) REF SC004: 6.2 KG / 5.6 KG
  REF SC002: 5.0 KG / 4.6 KG
  REF SC003: 2.5 KG / 2.3 KG

3. Manufacturing

The surgical clipper and disposable clipper blades are manufactured to specification under hygienic conditions in an especially developed production process.

The manufacturing process fulfills the requirements of ISO9001:2008 and ISO 13485:2016

Manufacturer: ME Medical AG, Switzerland

Country of origin: China, P.R.C.

4. Description

This is a surgical clipper is a device used for removing body hair prior to a (surgical) intervention or medical treatment. It is to be used by medical professionals and nurses.

This surgical clipper (shaving machine) operated by a re-chargeable lithium battery. The surgical clipper consists of a shaving machine (containing the battery), a disposable single-use blade (to be attached to the machine) and a charging station.

The instruction manual for use attached to each box of REF SC004 applies.

This surgical clipper is operated with a rechargeable lithium battery. It requires 120 minutes to charge/re-charge the battery.

5. Technical Data

Motor voltage:	3,7 Volt direct current	
Current without load:	0,18A	
Current at full load:	0,7A	
Rotation per minute:	5’500	
AC adapter:	IN PUT: 100-240 – 50/60Hz 0.4A OUT PUT:5.0Vdc 2A	
Charging time:	120 minutes	
Battery Operating time:	150 minutes	
Battery:	Li-ion 3.7V ICR 18650MAB 1800mAh	
Battery level indicator	LED digital display	
Overcharge protection	yes	

Degree of protection from fluids: IPX 7 (according regulation EN60259)

Class of electric insulation: II (according regulation CEI 62-5)

Net weight of clipper (with blade): 142 g / without blade 132 g

Dimensions of clipper (with blade) 151x46x35mm

Cutting width of blade	36 mm	(SC002 & SC003)
Cutting depth of remaining hair	0,3 mm	(SC002 & SC003)
Noise level	about 60 dB	
Warranty	2 years	
Cleaning	Soap and water. Rinsing with cold or warm water And drying with clean towel.	
Disinfection	Disinfecting swap, disinfectant, antimicrobial soap.	
Water resistance	the clipper can be submerged in water at max. 1 meter depth for maximum 30 minutes.	

6. Intended Purpose/Use

This surgical clipper is a device used for removing body hair prior to a (surgical) intervention. It is to be used by medical professionals and nurses.

7. Medical device classification

Intended to remove body hair prior to a (surgical) intervention. This surgical clipper is registered in the EU as medical device Class I according to Rule X Annex IX of the Council Directive 93/42/EEC concerning medical devices.

8. CE-Certification

The Surgical Clipper ME Medical Model No. SC004 is following these requirements of European Council Directives:

- The EMC Directive 2014/30/EU
- The Low Voltage Directive 2014/35/EU
- CE MDR IEC 60101-1:2005
- The IPX7 Standard according EN 60335-2-8:2015 + A1:2016, EN 60335-1:2012 + A11:2014 + A13:2017 + A1:2019 + A14:2019 + A2:2019
- The RoHS Directive (EU) 2015/863 amending 2011/65/EU

The Manufacturer has designed and tested the products in accordance with directives 2014/30/EU and of the directive 2014/35/EU. The CE mark placed on the products is related to the stated directives.

Complied with the following Standards:

EMC	EN IEC 55014-1:2021
	EN IEC 61000-3-2:2019+A1:2021
	EN 61000-3-3:2013+A1:2019
	EN IEC 55014-2:2021
LVD	EN 60335-2-8:2015 + A1:2016
	EN 60335-1:2012 + A11:2013 + A13:2017 + A1:2019
	EN 62233:2008

9. Biological evaluation and biocompatibility (DIN EN ISO 10993)

The metal and the ABS plastic present in this surgical clipper are biologically safe providing the device is used appropriately and for the purposes intended.

The starting materials used to produce this surgical clipper are of such purity that the correct use of the product is considered completely safe.

To date this company has received no notification of incidents involving this ME Medical product, neither has there been a need for a recall of this surgical clipper for reasons of quality.

The purpose of this documentation and of the statements made therein is to show that there is no risk involved in the use of this surgical clipper, and that – as it says in the Essential Requirements of the Council Device 93/42/EEC concerning medical devices – this surgical clipper "is designed, manufactured and packaged in such a way that it will not compromise the clinical conditions or the safety of patients, or the safety and health of users or other persons when used under the conditions and for the purposes intended".

10. Stability

Storage and transport conditions: -20°C to +50°C; 10% to 1 00% RH, 50 to 1 06kPa.

Storage conditions: +0°C to +40°C; 30% to 75% RH, 70 to 1 06kPa

11. Disposal

Incineration of the product (the device should not be disposed of on a tip) will generate CO_2 Iron oxide, of the packaging CO_2 and H_2O.

Used surgical clippers (containing a rechargeable lithium battery) should be returned to the shop/sales point or to the dangerous substances collection point for disposal. Due attention has to be given to current local legislation, norms and guidelines, regulating the disposal of refuse.

ME Medical AG
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Signed by:
Mr Urs Eisenring
(Director, Medical & Regulatory Affairs)

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