Technical Data Sheet

Omnistrip®

Specification.-No.: **D 9.2010**
Department: **QSI / QSS**
Date: 2001-02-13

CHANGE PROTOCOL

Page /Edition	replaces Page/Edition	Reason for Change
1-2 from 20.10.1999	--------	New Technical Data Sheet
1-2 from 13.02.2001	1-2 from 20.10.1999	Presentations changed.

Department	Date	Signature
Quality Assurance (QSI) Information System		

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1. General Product Description

Omnistrip® is made of a carded polyester-/polyamide nonwoven, which is coated with an acrylic pressure sensitive adhesive.
Omnistrip® has rounded ends, is conformable and stretchable, with a high porosity, permeability and breathability and good adherence to the skin.

Classification for sterile medical devices class IIa, acc. EEC-Directive

2. Application / Indication

Omnistrip® is a wound closure strip, which is used instead of thread suturing in general or specific surgery for closing of accidental wounds and scalpel incisions by adhering the strip to the skin and thereby bringing the wound flaps together.

3. Presentations

Sterile, sealed in peel-pack:

dimensions:	3 mm x 76 mm
	6 mm x 38 mm
	6 mm x 76 mm
	6 mm x 101 mm
	12 mm x 101 mm
	25 mm x 127 mm

4. Composition / Material

Backing:	Carded polyester-/polyamide nonwoven, binder bonded
Adhesive:	Acrylic pressure sensitive adhesive

5. Sterilization

Omnistrip® is gamma-sterilized.

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6. Labelling

Omnistrip® is labelled in accordance with the requirements of the "Medizinprodukte –Gesetz" (Medical Devices Act of the Federal Republic of Germany which implements Council Directive 93/42 EEC on medical devices into German law) and bears the CE-mark of conformity.

Lot-No. with 8-digit code:
e.g.:

1	07	XXXXX
year	week of production	for internal purposes only

Shelf life: Shelf life is 5 years.

7. Packaging

Omnistrip® packed into peel-able pouches made of surgical grade medical paper, into folding box; transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

13 February 2001

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