# **EC** Certificate

### mdc medical device certification GmbH

Notified Body 0483 herewith certifies that



for the scope

surgical dressings and other products for medical use (see annex)

has introduced and applies a

## Quality System

for the design, manufacture and final inspection.

The mdc audit has proven, that this quality system meets all requirements according to

## Annex II – Section 3 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

This certificate is valid until:

2014-06-10 0239.01.11/0

Certificate registration no.: Report no.:

E 0239.01 / 2009-06-10

Stuttgart

2009-06-10

Head of Certification Body





Phone: +49-(0)711-253597-0 Fax: +49-(0)711-253597-10 Internet: http://www.mdc-ce.de

#### Annex of the certificate

No. 0239.01.11/0

dated 2009-06-10

product	UMDNS	risk class				
		- 1	lla	IIb	III	
swab, X-Ray	10-965		Х			
dressings	11-315		Х			
gauze, germicidal	11-324			00000	Х	
surgical glove	11-883		Х			
lab sponge	12-370		Х			
gauze ball, X-Ray	13-705		Х			
cover	15-571		Х			

Head of Certification Body



# **EC** Certificate

### mdc medical device certification GmbH

Notified Body 0483 herewith certifies that



NOBA Verbandmittel Danz GmbH & Co. KG Höltkenstraße 1 - 5 58300 Wetter Germany

for the scope

sterile disposable products (see annex)

has introduced and applies a

## Quality System

for the aspects of manufacture concerned with securing and maintaining sterile conditions as specified in Annex V, Section 3.

The mdc audit has proven, that this quality system meets all requirements according to

## Annex V – Section 3 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V. Section 4.

This certificate is valid until: Certificate registration no.: 2014-06-10 0239.07.11/0

Report no.:

E 0239.07 / 2009-06-10

Stuttgart 2009-06-10

Head of Certification Body





Phone: +49-(0)711-253597-0 Fax: +49-(0)711-253597-10 Internet: http://www.mdc-ce.de

#### Annex of the certificate

No. 0239.07.11/0

dated 2009-06-10

product	UMDNS	risk class				
		1s/m	2a	2b	3	
adhesive strips	10-026	Х				
adhesive dressings	10-276	Х				
umbilical clips	10-876	Х				
swabs	10-965	Х				
dressings	11-315	Х				
padding bandage	11-326	Х				
examination glove	11-882	Х				
clothing, operating room, disposable	11-901	Х				
tongue depressors	12-374	Х				
bandages	13-369	Х				
gauze ball	13-695	Х				
tubular bandages	13-785	Х				
applicator	13-912	Х				
urinary catheterization / collection kits	14-292	Х				
surgical dressings, other	15-203	Х				
disposable drapes	15-705	Х				
incontinence pads	16-498	Х				
adhesive films	17-428	Х				

Head of Certification Body



# **EC** Certificate

### mdc medical device certification GmbH

Notified Body 0483 herewith grants



NOBA Verbandmittel Danz GmbH & Co. KG Höltkenstraße 1 - 5 58300 Wetter Germany

for the scope

Jodotamp<sup>®</sup>, medicated ribbon gauze strip made of cotton Jodomull®, medicated gauze bandage made of cotton

## EC Design Examination Certificate

The examination of the design of the product by mdc has proven, that according to the report of the file review no. E 0239.11 / 2009-06-10 the design meets the requirements according to

### Annex II - Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

This certificate is only valid in connection with a valid mdc certificate according to Annex II - Section 3 for the above mentioned products.

This certificate is valid until:

2014-06-10

Certificate registration no.:

0239.11.11/0 E 0239.11 / 2009-06-10

Report no.: Stuttgart

2009-06-10

Head of Certification Body





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