

# CERTIFICATE

No. Q1N 15 10 90237 005



Product Service

**Holder of Certificate:**

**NOBAMED Paul Danz AG**

Höltkenstr. 1-5  
58300 Wetter (Ruhr)  
GERMANY



**Facility(ies):**

NOBAMED Paul Danz AG  
Höltkenstr. 1-5, 58300 Wetter (Ruhr), GERMANY

NOBAMED Paul Danz AG  
Koninerstraße 10, 44625 Herne, GERMANY

NOBAMED Paul Danz AG  
Wideystraße 58, 58452 Witten, GERMANY

**Certification Mark:**



**Scope of Certificate:**

**Design and development, production and distribution of medical devices for general and special wound treatment, surgical products, dressings, bandages, plasters, incontinence products and products for use on the ward and in general practice, ambulance and patient care**

**Applied Standard(s):**

EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:**

713070650

**Valid from:**

2016-02-04

**Valid until:**

2018-06-10

**Date,** 2016-02-04

Hans-Heiner Junker





Product Service

# EC Certificate

## Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 15 10 90237 006

**Manufacturer:** NOBAMED Paul Danz AG

Höltkenstr. 1-5  
58300 Wetter (Ruhr)  
GERMANY



**Facility(ies):**

NOBAMED Paul Danz AG  
Höltkenstr. 1-5, 58300 Wetter (Ruhr), GERMANY

**Product  
Category(ies):**

Swabs, Balls, Wound Dressings, Padding Dressings  
and Bandages, Gloves, OR-Clothes, Drapes,  
Bandages, Plasters, Umbilical Cord Clamp,  
Tongue Depressors, Customized Procedure Trays  
(s. Attachment)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** 713070650

**Valid from:** 2016-02-04

**Valid until:** 2020-06-10



**Date,** 2016-02-04

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

**Attachment for Certificate No. G2S 15 10 90237 006  
valid from 2016-02-04**

Productgroup/Productname	Classification	Rule
<b>Swabs:</b>		
Gauze swabs	l s	4
Absorbant swabs	l s	4
Slit swabs	l s	4
Eye pads	l s	4
Noba swabs	l s	4
Gauze dressing	l s	1
Nobatamp	l s	4
<b>Balls:</b>		
Gauze balls	l s	4
Noba Cellulose Swabs	l s	4
Nobamed	l s	4
Cotton applicator	l s	4
<b>Wound Dressings:</b>		
First aid dressing	l s	4
Rapid wound dressing	l s	4
Wound sheet	l s	4
Ruda dressings	l s	4
Rudawatch dressing	l s	4
Noba dressings	l s	4
Nobafilm	l s	4
Nobaderm	l s	4
<b>Padding bandages and dressings:</b>		
Nobapad	l s	1
Cotton wool	l s	1
Nobatricot	l s	1
<b>Gloves:</b>		
Nobafol	l s	5
Nobaglove	l s	5
Washing glove	l s	1
Cotton glove	l s	1
<b>OR Clothes:</b>		
Nobadress	l s	1
<b>Bandages:</b>		
Stockinette bandage	l s	1
Nobafix	l s	1
Nobacrepp	l s	1
Nobalan	l s	1
Nobalastik	l s	1
Umbilical cord band	l s	1



Product Service

**Attachment for Certificate No. G2S 15 10 90237 006  
valid from 2016-02-04**

<b>ENT:</b>		
Tongue depressor	l s	5
<b>Adhesive Plaster:</b>		
Ruda Plaster	l s	4
Umbilical cord clamp	l s	1
<b>Drapes:</b>		
Noba Drape	l s	1
<b>Customized set-systems</b>	l s	1, 4, 5
e.g Set for dressing changes, Injection Set, Drainage Set, Nobacath, Set for taking out of stitches, PEG-Set with parts like swabs, gloves, drapes, forceps		

Munich, CRT2, 2016-02-04

Hans-Heiner Junker





Product Service

# EC Certificate

## Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

No. G1 15 10 90237 007

**Manufacturer:****NOBAMED Paul Danz AG**

Höltkenstr. 1-5  
58300 Wetter (Ruhr)  
GERMANY

**Facility(ies):**

NOBAMED Paul Danz AG  
Höltkenstr. 1-5, 58300 Wetter (Ruhr), GERMANY

**Product  
Category(ies):**

**Gauze Dressings, Gauze Balls, Surgical Cloths,  
Covers, Surgical Gloves, Customized Surgical  
Procedure-Sets, Wound Dressings, Ropes (s. Attachment)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:**

713070650

**Valid from:**

2016-02-04

**Valid until:**

2020-06-10



Hans-Heiner Junker

**Date,** 2016-02-04

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

**Attachment for Certificate No. G1 15 10 90237 007  
valid from 2016-02-04**

Productgroup/Productname	Classification	Rule
<b>Gauze Dressings:</b>		
Gauze Dressing	Ila	7
<b>Gauze Balls:</b>		
Gauze balls, X Ray detectable thread	Ila	7
Ear operation swab, X Ray detectable thread	Ila	5
Preparation ball, X Ray detectable thread	Ila	7
Gyn Tampon, X Ray detectable thread	Ila	5
<b>Surgery cloth:</b>		
Laparotomy Sponge	Ila	7
<b>Covers:</b>		
Wound hook cover	Ila	7
Instrument cover	Ila	7
<b>Surgical Gloves:</b>		
Nobafeel	Ila	6
<b>Customized surgical procedure set</b>		
e.g. V-Set and Surgery Set with components as Gauze swabs, gauze dressing, needles, syringe	Ila	4, 6, 7
<b>Wound Dressings/Ropes:</b>		
Nobacarbon	Ila	4
Nobacarbon Ag	Ilb	4
Nobagel	Ilb	4
Nobacolloid	Ilb	4
Nobaalgin	Ilb	4
Jodomull/Jodotamp	III	13

Munich, CRT2, 2016-02-04

Hans-Heiner Junker





Product Service

# EC Certificate

## EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)  
(Devices in Class III)

No. G7 15 10 90237 008

**Manufacturer:****NOBAMED Paul Danz AG**

Höltkenstr. 1-5  
58300 Wetter (Ruhr)  
GERMANY

**Product:**

Wound Care Products, Drug/Device Combination

**Model(s):**

Jodotamp® medicated ribbon gauze strip made of cotton  
Jodomull® medicated gauze bandage made of cotton

**Parameters:**

Jodotamp® medicated ribbon gauze strip made of cotton  
REF 632401 1cmx5m  
REF 632402 2cmx5m  
REF 632403 3cmx5m  
REF 632405 5cmx5m  
REF 632408 8cmx5m

Jodomull® medicated gauze bandage made of cotton  
REF 294106 6cmx5m  
REF 294208 8cmx5m  
REF 294310 10cmx5m

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

**Report no.:**

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**Valid until:**

2019-06-10



Hans-Heiner Junker

**Date,** 2016-02-04

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