



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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**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



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<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

