



QUALITY PLUS

nopa<sup>®</sup> instruments

thank you for choosing  
**nopa** instruments...

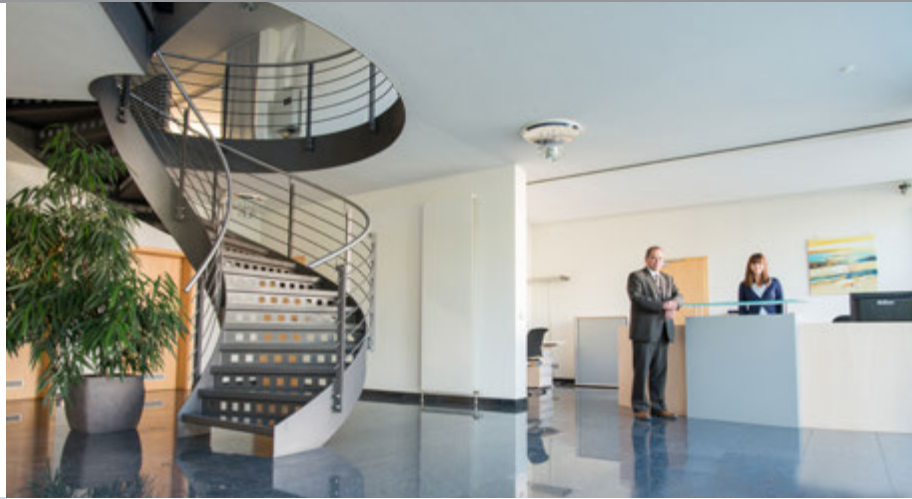
...you obviously have good taste



The head office of **nopa instruments** is located in Tuttlingen/Germany, the "World Centre of Medical Technology"



- >> Company founded in 1982
- >> Company founders **Norbert Pauli** and Monika Pauli
- >> Decades of experience in the field of surgical and endoscopic instruments, as well as sterilization containers
- >> One of the first companies in its sector to be certified since 1995 according to international standards and norms



Chamber of Commerce and Industry  
Schwarzwald-Baar-Heuberg  
(ID No. 36325694)



Chamber of Crafts Konstanz  
(Company No. 31659)




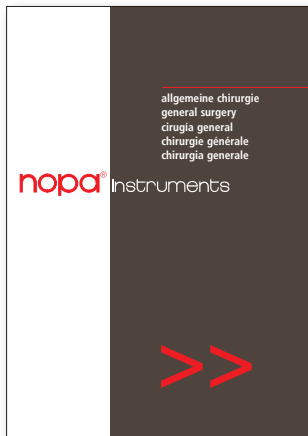
District Court Stuttgart  
(Registration No. HRB 450413)



We are **members in different committees** and participate in various scientific studies:

- >> Instrument sterilization and cleaning
- >> Instrument sterilization
- >> Validation processes

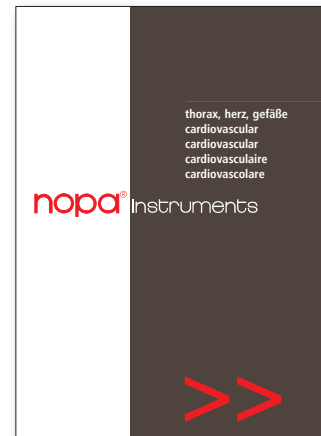
Our product catalogues can be found in electronic form on our website.   
We are also happy to make our catalogues available to you as printed books.



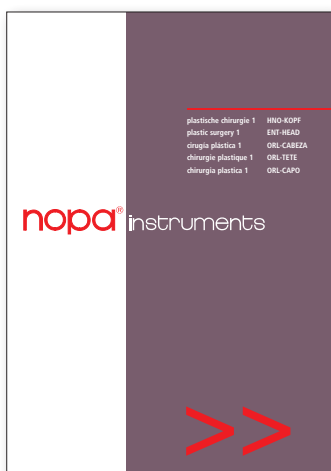
A-K general surgery  
illustrated on 664 pages



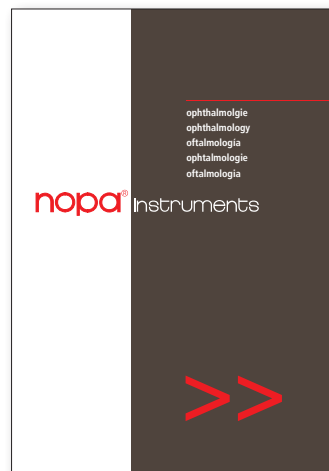
KB-KC gynecology, obstetrics and  
urology, illustrated on 574 pages



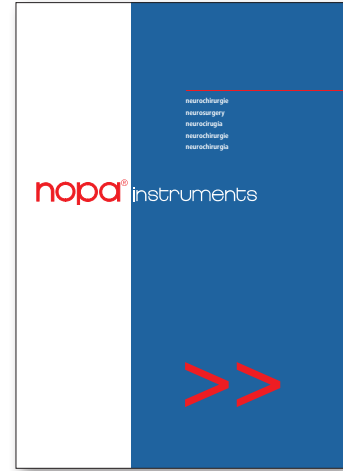
KK cardiovascular  
illustrated on 380 pages



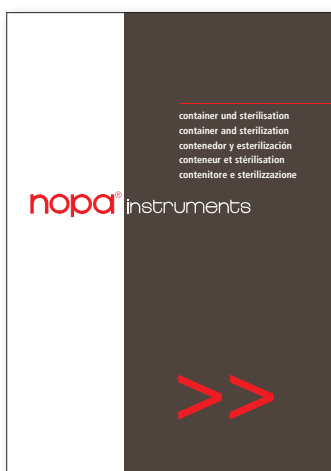
KL-KO plastic surgery ENT-HEAD  
illustrated on 500 pages



KP ophthalmology  
illustrated on 238 pages



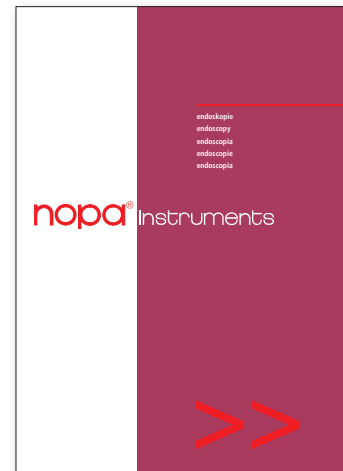
KS neuro surgery  
illustrated on 201 pages



KYE container and sterilization  
illustrated on 136 pages



P dental and oral  
illustrated on 404 pages



X endoscopy  
illustrated on 266 pages





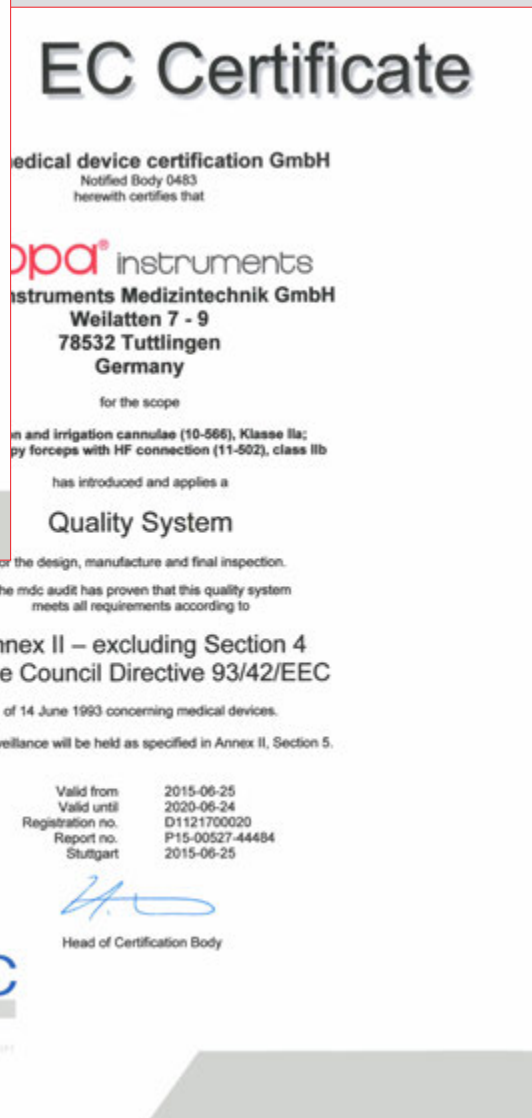
Our product range includes

**16,000 products**  
sales in **over 120 countries**





nopa instruments has a quality management system in accordance with the standard ISO 13485, based on the legislation 93/42/EEC of 14.06.1993 for medical instruments.



Our complete certificates are available as download on our website





## DECLARATION OF CONFORMITY

### EG-Konformitätserklärung EC-Declaration of conformity

Anbieter:  
Supplier: nopa instruments Medizintechnik GmbH

Anschrift:  
Address: Weilatten 7-9  
78532 Tuttlingen

Medizinprodukt:  
Medical Device: wiederverwendbare chirurgische Instrumente  
*reusable surgical instruments*  
gemäss Anlage 1 Produktgruppenliste  
see attachment 1 product group list  
ab Fertigstellungsdatum 01.01.2010  
bis Fertigstellungsdatum 24.06.2018

Wir erklären in alleiniger Verantwortung: Das oben beschriebene Medizinprodukt ist konform mit:  
We declare under sole responsibility: The medical device described above is in conformity with:

Dokument-Nr. Document No.	Titel (nur harmonisierte Normen) Title	Ausgabe/ Ausgabedatum Edition / Date of issue
93/42/EGW	Richtlinie 93/42/EWG des Rates über Medizinprodukte Anhang VII Council Directive 93/42/EEC concerning medical devices App. VII	14.06.1993
2007/47/EG	Richtlinie 2007/47/EG des Europäischen Parlaments und des Rates Council Directive 2007/47/EG of the European Parliament and of The council	05.09.2007

Tuttlingen, 22.06.2015

Stefan Kappeler, QMB  
(Name, Funktion / Name, Function)

(Unterschrift / Signature)

FB Konformitätserklärung Klasse I

Please ask for  
EC-Declaration of conformity

### Produktgruppenliste Product group list

Produktgruppen-Bezeichnung Product group description	UMDNS-Nr.	Risikoklasse	Regel
Klemmen / Hemostats	10961	1	6
Pinzetten / Forceps	14257	1	6
Scheren / Scissors	13480	1	6
Skalpelle / Scalpels	12252	1	6
Nadelhalter / Needle holders	12726	1	6
Tupferzangen / Sponge forceps	11791	1	6
Wundhaken / Retractors	13373	1	6
Sonden / Sondes	13117	1	6
Verband / Dressing	13706	1	6
Kanülen / Special needles	12729	1	6
Narkose / Anaesthesia	12293	1	6
Diagnostik / Diagnostics	14255	1	6
Orthopädie / Orthopaedic	11507	1	6
Gynäkologie / Gynecology	11788	1	6
Urologie / Urology	17633	1	6
Darm, Magen, Mastdarm / Intestines, Stomach, Rectum	13665	1	6
Mammoplastik / Mammoplasty	13373	1	6
Herz, Thorax / Cardio vascular	10836	1	6
Mund, Zunge, Tonsillen/ Oral instruments, Tonsils	15672	1	6
Otologie / Otolaryngology	13662	1	6
Rhinologie / Rhinology	13632	1	6
Clips/clip	10896	1	6
Säge/saw	13448	1	6
Zange / Forceps	11774	1	6
Haken / Hook	12028	1	6
Zange Fixation / Forceps fixation	11781	1	6
Mikrochirurgieinstrument / Micro surgery instrument	15621	1	6
Spreader / Spreader	13707	1	6
Stanze / Punch	13226	1	6
Elevatorium / Elevator	11507	1	6
Verschiedenes / Various items	15661	1	6

Stand 22.06.2015

Datensatz  
FB Produktgruppenliste Klasse I.doc

Revison  
A

erstellt am  
21.03.2010

von  
Kappeler

zuletzt geändert am  
09.04.2013

von  
Kappeler

Seite  
1 von 1

Druck  
0 74 62 / 94 50 90

Study by the **University Hospital of Freiburg:**

Comparison of nopa instruments to the instruments used in the clinic



### MPE – nopa instruments Medizintechnik GmbH

<b>Title of the study:</b>	
Market preference analysis (MPE-nopa)	
Evaluation of different instruments from the company nopa instruments Medizintechnik GmbH	
<b>Client:</b>	
nopa instruments, Medizintechnik GmbH, Weilatten 7-9, 78532 Tuttlingen	
<b>Test product(s):</b>	
HALSTED-MOSQUITO FCPS STR 12.5 CM CRILE-RANKIN FORCEPS CVD 16.0 CM BACKHAUS TOWEL FORCEPS 8.0 CM STANDARD DRESSING FORCEPS STR 14.5 CM STANDARD TISSUE FCPS. 1X2 T STR 14.5 CM STANDARD OPER.SCS. STR.SH/BL 14.5 CM MAYO DISS.SCS TUC STR BL/BL 17.0 CM METZENBAUM-NELSON SCS CVD BL/BL 18.0 CM SCALPEL HANDLE NO.3 SCALPEL HANDLE NO.4 CRILE-WOOD NEEDLE HOLDER TUC 15.0 CM MAYO-HEGAR NEEDLE HOLDER TUC 18.0 CM CUSHING RECTRACTOR 12 MM 20.0 CM VOLKMANN RETR.BLUNT 3 PRONGS 21.5 CM NOPA E-CONTAINER 285x280x100MM, RED WIRE BASKET, 255 X 245 X 50 MM	
<b>Objective of the study:</b>	
Evaluation of handling during surgery / application of the aforementioned surgical products	
<b>Study design:</b>	<b>Case number (planned and analysed):</b>
Survey of OP personnel by means of a questionnaire	N=25 (25 different applications in the study period)
<b>Study procedure:</b>	
Survey of OP personnel by means of a questionnaire with regard to the evaluation of different instruments from the company nopa-instruments	
<b>Study conducted by:</b>	
University Clinic Freiburg, Study Centre	
<b>Date of the beginning of the study:</b>	<b>Date of completion of the study:</b>
01.04.2013	31.12.2013
<b>Summary of the results:</b>	
If an average value is derived from the individual assessments, the products used reach a value of 6.16 (based on 0 = bad, 10 = very good). See reverse for details, diagram 1	
<b>Conclusions:</b>	
In all, the nopa instruments were assessed by the participants to be equal in value to existing instruments. On a scale from 0-10, both the evaluation of almost all of the instruments and the overall rating were above the average value of 5.0, with the highest value even reaching 7.43. See reverse for details, diagram 2 and diagram 3	





Diagram 1

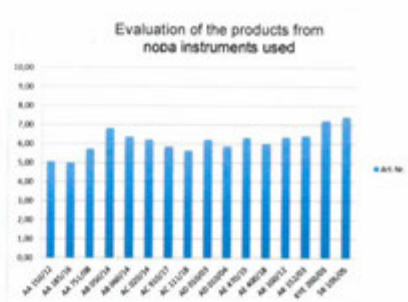


Diagram 2

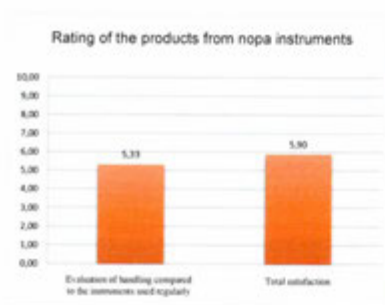


Diagram 3

Authors:

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Project coordinator  
Study Centre

*B. Grotejohann*  
Signature

*Freiburg 16.02.2014*  
Place, date

Julia Maurer  
Project assistant  
Study Centre

*J. Maurer*  
Signature

*Freiburg 26.02.2014*  
Place, date

Erik Hummel  
Managing Director

*E. Hummel*  
Signature

*Freiburg 28.02.2014*  
Place, date

nopa® instruments

nopa®  
**TUC**

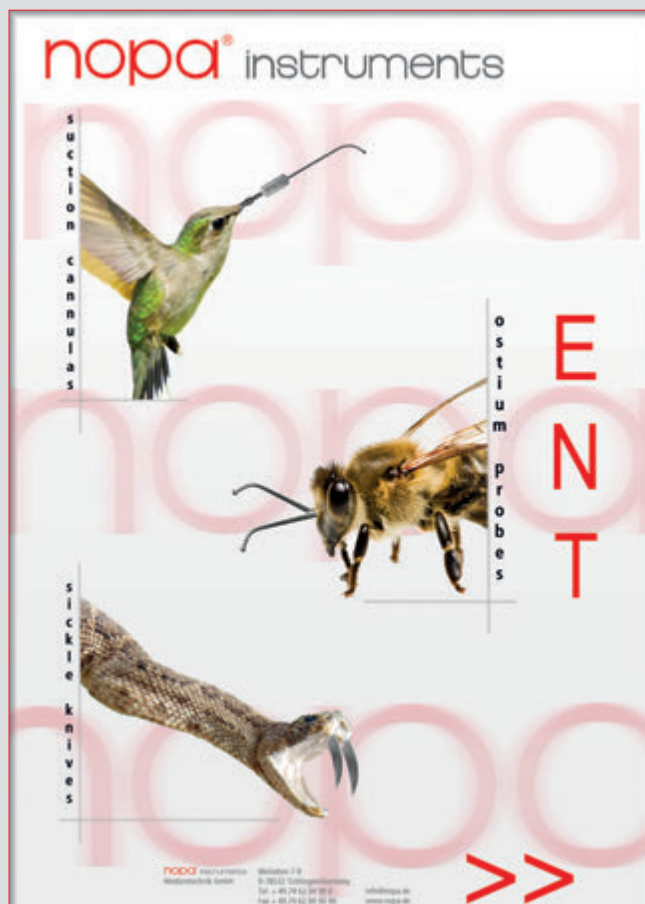
**SUPER CUT TUC**

**SUPER CUT**

**ATRAU**  
nopa®

nopa® **DIAMOND**

POSTERS



Poster ENT



Poster Sterilization

**nopa<sup>®</sup>** instruments



**SUPER CUT**

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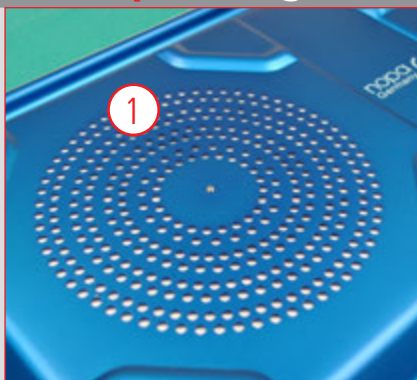
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**nopa instruments** posters in the format 50 x 70 cm are also available for your exhibition space..

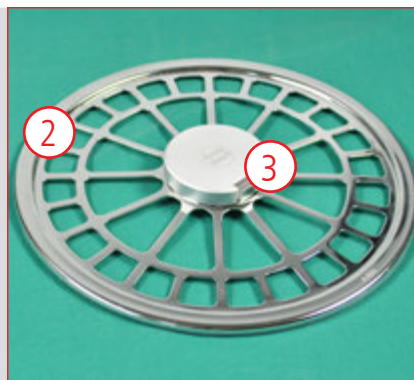


Validation certificate  
refer to page 14

## Our **nopa** Design



① Round perforations  
in the lid



② Filter holder with  
proven design

③ Proprietary and protected  
closure system



④ Special **nopa** closure

⑤ Silicone covered and ergono-  
mically shaped handles

⑥ Prominent black, continuous  
front panel

⑦ Corner protection

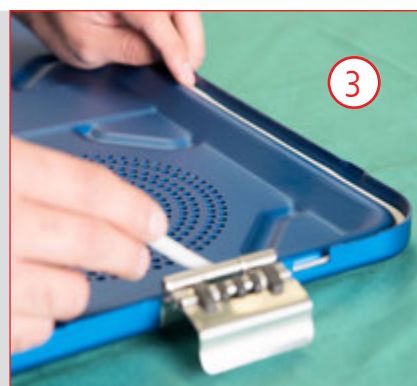
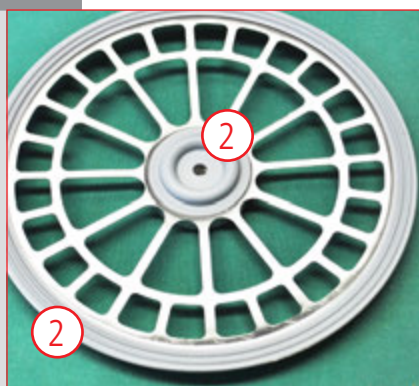




On request, we will mark the container with your company name or logo by laser.



## Our **nopa** Quality



- ① Assembling of filter holder
- ② Gluing of inner and outer ring onto the filter holder
- ③ Gluing of the silicone seal into the inside of the container lid

**Implemented and checked**  
by our  
highly qualified team

Sterilization certificate available as download on our website. 

# Certificate

**SMP GmbH    Testing, Validation, Research**

hereby certifies the

## validation of sterilization containers

of the company

**nopa instruments Medizintechnik GmbH**  
**Weilatten 7-9**  
**78532 Tuttlingen**  
**Germany**

*Tested and validated with original  
nopa instruments filters and  
original nopa instruments components!*

The SMP investigation, with the project no. 04 nopa container KYE 200/91. The dimensions of the container are high, has a closed bottom and a perforated filter. It has the most demanding ratio between filter area and volume. It represents the "worst case". In this investigation, it fulfils the requirements of the following standard process, i.e. the achieved sterility, after going through the process:

**DIN ISO 14726**  
**DIN EN 8536-1**



SMP GmbH Prüfen; Validieren; Forschen  
Sitz: Tuttlingen, HR B 2116, USt-IdNr.: DE209756841  
Bankverbindung: Kreissparkasse Tuttlingen  
Kto: 2 613 392, BLZ 641 500 20

Ges.  
Ges.

## SMP GmbH - Service for medical products Paul-Ehrlich-Strasse 40 - 72076 Tübingen – Germany

### Founders

Surgeon	Dr. Gerhard Bueß / University of Tübingen
Physician and engineer	Dr. Thomas W. Fengler
Clinical hygienist	Dr. Peter Heeg / University of Tübingen
Physicist	Dr. Rudolf Reichl
Managing director	Klaus Roth
Physicist, private lecturer	Dr. Ludger Schnieder
Physician	Dr. Marc O. Schurr

The increased demand for the validation and testing of cleaning processes for surgical instruments was what initiated the founding of SMP GmbH. Based on the skilled expertise of the company founders in the area of surgical instruments and hygiene, as well as their experience in many different joint research projects, SMP GmbH offers services which allow medical companies to make substantiated statements about their products in the area of reprocessing and hygiene.



## FROM THE FIELD

## Keywords

- steam sterilisation
- surgical instruments
- process challenge device
- resistometer

ORIGINAL PAPER

## Steam Sterilisation of Reusable Surgical Instruments

## Effectiveness Limits

J. Haas, H. Henn\*, U. Junghanss, K. Kobel, D. Toth, H.C. Weiss and Working Group Instrument Preparation\*

The aim of the present study was to investigate various process challenge devices (PCDs) already used in a previous study focusing on the sterilisability of reusable surgical instruments (Sterilisability Study), but now using shorter sterilisation times. Sterilisation processes were conducted in a resistometer (134 °C) as well as in a test steriliser at temperatures of 132 °C (270 °F) and 134 °C (273 °F), using different hold times. The results obtained for the resistometer showed that in the "Thread" model no test organisms could be detected after a sterilisation time of 90 s. In the "Gap" and "Seal" models positive results were obtained after this sterilisation time because of the design features of these models. Complete inactivation of test organisms was achieved for the biological indicators used after 180 s. The other models used, i.e. the "Hose" model, both with and without a volume-reducing insert, and the two "Sliding surface" models, with metal as well as with plastic, continued to show microbial growth even after a 5-min exposure time.

The following results were obtained for the test steriliser: For the majority of tests conducted, with and without a load, in the test steriliser, there was no evidence of any test organism remaining after a hold time of either 90 s or 180 s and a temperature of 134 °C.

For the "Seal" and "Hose with insert" models, test organisms were detected in some cases, and this was confirmed by running a confirmatory test.

In the tests carried out at a temperature of 132 °C with hold times of 2 and 4 min, test organisms were recovered only in the "Hose with insert" model for the 2-min hold time, both with and without a ballast load.

## Introduction

After being used on a patient, medical devices must be reprocessed to render them free of contamination, which could give

rise to infection, for reuse on another patient. Decontamination processes that meet specific requirements must therefore be used to reprocess such medical devices. A maximum degree of microbial inactivation must be assured so that the sterility of the devices can be demonstrated. Whether a device can be viewed as being sterile and suitable for the intended purpose is something that must be critically appraised within the framework of quality assurance. DIN EN 556 and DIN EN 14937 contain information on this, e.g. a device can be deemed to be sterile if the theoretic value stipulating that no more than one microorganism may be present in one million sterilised units of the final product (i.e. sterilised medical device) is assured. Since in principle it is not possible to inspect each and every device for "sterility", in our opinion surrogate values have to be used to guarantee the requisite sterility. Hence a medical device may only be designated as "sterile" if a validated sterilisation process has been used and the instructions specified by the respective medical device manufacturer have been observed.

Since the hold time used in Anglo-Saxon countries is generally 3 min, additional tests to the Sterilisability Study were carried out to investigate and critically appraise the effectiveness of such a process.

## Materials and Methods

The effectiveness of a sterilisation process can in theory be demonstrated by means of the microbial survival curve. The exposure time needed to assure a specified survival probability of the microorganisms can thus be calculated and achieved. The influence exerted by constant physical

variables on the respective microbial population is generally a reaction of the first order. Consequently, the half-logarithmic depiction of the time in relation to the microbial count present gives a linear inactivation curve, while taking account of the reaction kinetics constants. However, it must be borne in mind that marked differences are seen in terms of the microorganism species and their spores and also as regards the prevailing environmental conditions. The decimal reduction times (D-value) is the yardstick used to show the resistance of a microbial population.

In our tests we used the following types of biological indicators:

- Spore strips of *Geobacillus stearothermophilus* ATCC 7953 with an average baseline microbial count of  $1.0 \times 10^6$  cfu/germ carrier (filter paper) and a D-value of 1.5 min at 121 °C.
- Spore suspensions of *Geobacillus stearothermophilus* ATCC 7953 with  $2.6 \times 10^6$  cfu/ml and a D-value of 1.9 min at 121 °C. Direct inoculation of the respective process challenge device (PCD) described below was performed with  $10 \mu\text{l}$  spore suspension.

A resistometer manufactured by the firm Lautenschläger with individual programming facilities was used for the test series. The design of this apparatus meets the es-

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• For a list of members of the Working Group please see references at the end of the article

263

CENTRAL SERVICE | Volume 17 | 2009

and DIN EN 61010-1/2/4/11. The chamber capacity is 9.3 l.

A test steriliser manufactured by the firm Lautenschläger (Protocent 716) was used in conformance with DIN EN 285.

Process: pulsed prevacuum (120 mbar, 3-fold pulses).

Thermologgers manufactured by the firm Yokogawa, Model MV200, were used to verify the process parameters.

The PCDs used to simulate the myriad surgical instruments were PCDs that had been standardised on the basis of the findings obtained in the Sterilisability Study. Evaluation data showed the PCDs to be composed of different materials and of designs that were deemed to be difficult to sterilise:

- **Thread model:** This PCD simulates the type of thread found in many instruments (Fig. 2). To assure clear-cut microbial recovery, a metallic block with access from both sides was designed. Access was granted at both ends via a fine M10 fine thread. Two threaded pins, each measuring 25 mm in length, were screwed into the thread and tightened manually using a nut. Analysis by the working group revealed that of all the threads found in in-

struments, the

The PCD was contaminated using biological indicator strips that were placed in the hollow PCD and closed at both ends with the threaded pins.

- **Gap model:** This PCD was simulated by means of a clamp device with two metal surfaces, one placed on top of the other and pressed together by means of a clamping mechanism using screw pretensioning (Fig. 3). This construction allows for clear-cut microbial recovery and is intended as a means of simulating the gaps in instruments. Pretensioning by means of two clamping screws is defined as an additional worst-case feature.

For contamination purposes, the inoculated germ carrier was placed between the two forceps parts, with the grooved side facing outwards in each case so as to conjure up a worst-case scenario in respect of heat conduction. Using the metal ring, the metal plates, which had already been positioned, were fixed and tightened using the hexagon screws of the PCDs.

- **Seal model:** This PCD was simulated by the same PCD as used in the gap model,

see above diagram of gap model (Fig. 3); however, a silicone seal was placed additionally between the two metal plates. Here the silicone seal is pressed against the metal plate using screw pretensioning, thus simulating a seal.

The germ carrier was placed between the forceps item and silicone seal, and placed under tension using the metal plates and rings.

- **"Hose with insert" model:** This PCD simulates long lumens that are open at both ends. The PCD is used to check instrument hoses (tubes) and lumens that are open at both ends (Fig. 4). Here the spore carrier is placed in the hose chamber in the centre. The chamber contains a plastic insert reducing the existing volume. The germ carrier was placed in the plastic insert during sterilisation.

For the present model, a total hose length of 4000 mm was defined, representing a minimum length of 2000 mm for the steam penetration into a lumen open on one side.

The PCD was opened at one side and the germ carrier inserted into the PCD chamber and closed.

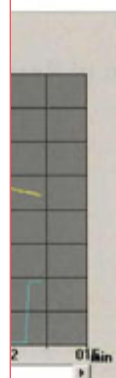
The germ carrier was placed in the model as described above.

- **(Metal) sliding-surface model:** The PCD is simulated by cocks that are defined as metal-metal pairs (Fig. 5). The two surfaces rubbing together are always composed of the cock chamber and cock plug. In this PCD model, the cock chamber and cock plug are always made of metal. But the cock plug is always pretensioned by means of a spring cap. This sliding surface has been defined as a worst-case feature for all sliding metal surfaces.

To contaminate, the internal contact surfaces of the cock were wetted with  $10 \mu\text{l}$  of the spore suspension and then dried. When assembled, the cock was set to "throughput".

- **(Metal-plastic) sliding-surface model:** The PCD is simulated by cocks that are defined as metal-plastic pairs (Fig. 5). The two surfaces rubbing together are always composed of the cock chamber and cock plug. In this PCD model, the cock chamber is always made of metal and the cock plug of plastic. But the cock plug is always pretensioned by means of a spring

## E FIELD



Thread represented a

Complete document (5 pages) is available as download on our website.

# MATERIALS USED

DIN 58298:2010-09												
Product Group				Elevators/Raspatories	Forceps	Scissors	Ring Forceps / Pliers	Bone Cutting Forceps/Bone Rongeurs/Bone Punches	Shank Forceps / Pliers	Conchotomes	Scalpels / Knives	Retractors
Group of nopa Item Numbers				KA,KO, PF,PI, PS,PT	AB	AC	AA,AB,AE, AF,AM,AP, KD,KA,KB, KC,KD,KK, KL,KM,KO, KS,PV,XK,	KA,KO	AM, KA,KB, KM,KS KU,PA, PB,PT, PU,PV,	KA,KO	AD,KA, KL,KM, KO,KS, KU,	AK,AP, KA,KB, KD,KI, KL,KM, KO,KS
Code letter according to ISO 7153-1	Material Number according to DIN EN 10088-1	Material Symbol according to DIN EN 1088-1	Hardness in Rockwell	Application								
B	1.4021	X20Cr13	42 - 50	x	x	x	x	x	x	x		x
A	1.4024	X15Cr13	40 - 48		x		x		x			x
D	1.4034	X46Cr13	50 - 58	x		x		x		x	x	
H	1.4117	X38CrMoV15	50 - 58	x		x		x		x	x	
N	1.4305	X8CrNiS18-9										x
M	1.4301	X5CrNi18-10										x
P	1.4401	X5CrNiMo17-12-2				x	x					x

EN ISO 7153-1:2000								
	C	Si, max	Mn, max	P, max	S	Cr	Mo	N
A	0,09 - 0,15	1	1	0,04	0,03 max	11,5 - 13,5		1 m
B	0,16 - 0,25	1	1	0,04	0,03 max	12 - 14		1 m
D	0,42 - 0,50	1	1	0,04	0,03 max	12,5 - 14,5		1 m
H	0,35 - 0,40	1	1	0,045	0,03 max	14 - 15	0,4 - 0,6	
M	0,07 max	1	2	0,045	0,03 max	17 - 19		8 -
N	0,12 max	1	2	0,06	0,15 - 0,35	17 - 19		8 -
P	0,07 max	1	2	0,045 max	0,03 max	16,5 - 18,5	2 - 2,5	10,5 -

material\_A\_en

overview of the high quality materials used



nopa® instruments

Probes / Trocars / Suction Tubes	Chisels / Bone Curettes	Mallets	Needleholder	Handle (hollow)	Handle (solid)
AL, AO, KK, KB, KC, PL	KA, KB, KC, KL, KM, KO, KU, PK, PM, XM	AR, KM, KO	AE, KS	AE, AK,	AK,
x	x		x		
x			x		
	x				
	x				
x	x	x			x
x				x	
x					

Div	DIN10088-1/AISI F899
max	1.4024 / 410
max	1.4021 / 420A
max	1.4034 / 420C
V:0,1 - 0,15	1.4117 / 420B
11	1.4301 / 304
10	1.4305 / 303
13,5	1.4401 / 316

22.09.2015



Dr.-Ing.

**storz**

Werkstoffberatung

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7262 Tuttlingen

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Ihre Nachricht vom

Mein Zeichen  
O/St.42655 Solingen  
06.12.11**analysis and hardness measurement of two instruments (A.-Nr.5075)***the OES-analysis (optical emission spectrometry)\**

sample	AC 100/14 Metzenbaum scissors GER.ST/ST 14.5 cm	KD 240/16 Doyen intestinal clamp straight 16.0 cm
C	0,34	0,21
Si	0,38	0,37
Mn	0,37	0,53
P	0,029	0,014
S	0,024	0,016
Cr	13,56	14,01
Ni	0,21	0,08
Mo	0,06	0,01
Al	0,005	0,007
Cu	0,14	0,01
Co	0,03	0,03
Ti	0,004	0,006
steel-grade	~ AISI 420	~ AISI 420
hardness in HV10**	529 – 542	434 – 437
~ HRC	~ 51,0 – 51,8	~ 44,0 – 44,2

\*result given in wt.-%; \*\* measured in the cross-section

**result:** The material composition, tested by an OES-analysis of the instruments corresponds to the American stainless steel grade AISI 420.

The hardness of the scissors was tested with 529 – 542 HV10 (~ 51,0 – 51,8 HRC). The clamp was measured with 434 – 437 HV10 (~ 44,0 – 44,2 HRC). Both fulfil the requirement of the standard.

# PRODUCTION PROCESS

Purchase and control of forgings

V

Check forgings and raw material

V

Drilling and milling

V

Adapting and connecting parts

V

Hardening and tempering

V

Check hardness

V

Grinding and polishing

V

Cleaning

V

Marking LOT number

V

Final inspection

V

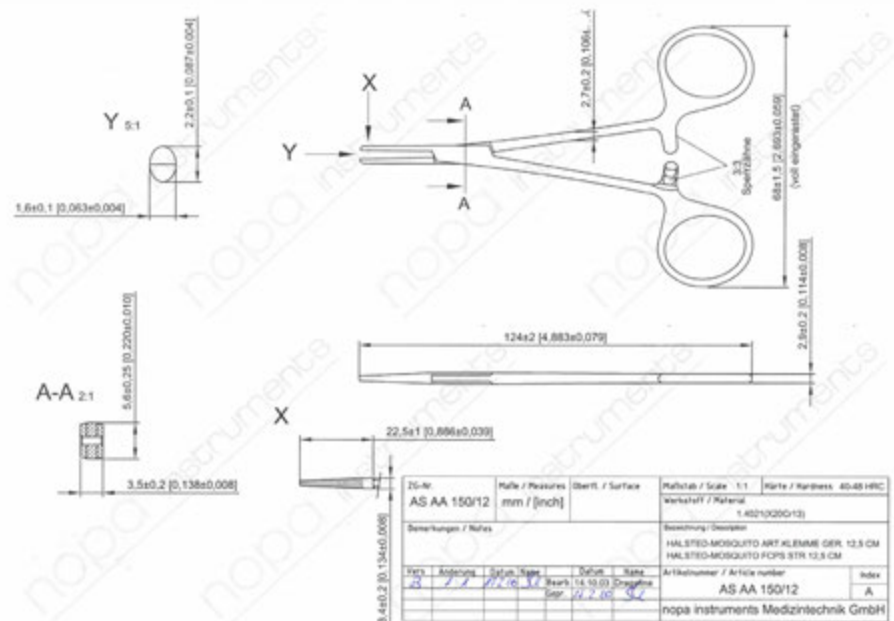
Check OK

V

Storage of the tested instruments



## Technical drawing



## "From raw materials to the finished instrument"

### Career history of a surgical forceps





## PRODUCTION AND TESTING

### PRINTS FROM OUR TESTING CENTRE



Surface treatment



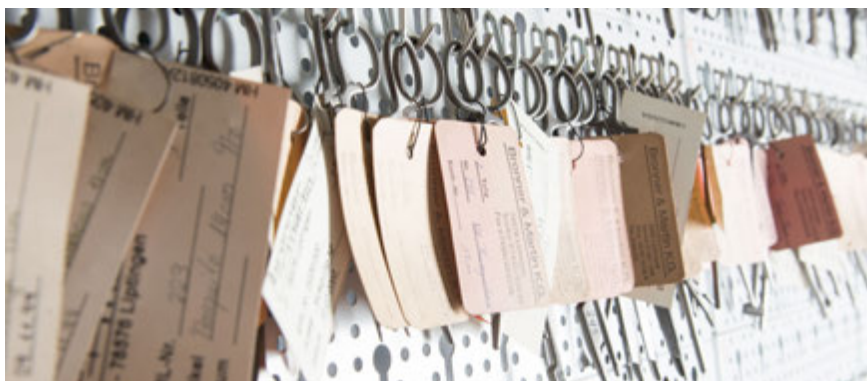
Testing of carbide inserts  
in needle holders



Cleaning and passivating of instruments



Hardness testing



sample of forgings, finished instruments  
or drawings for the identification and testing  
of the instruments



**PA 04 – Scissors****1.0 Description of the test method**

**1.1** Samples are taken according to AA-02.

**1.2** Fundamental way to handle scissors:

- A pair of scissors may never be opened abruptly to the extent that the back of the blade hits the shank, thereby creating dents.
- When cutting, lateral pressure must never be applied. The scissor blades could otherwise be damaged.
- There must never be residue of grinding and polishing dust on the cutting blade. This could damage the blade.

**1.3** Scissors identification:

- Compare the shape of the scissors using models and catalog material with regard to model and curvature.
- Check of total length using the catalog or a model  
Test equipment: calipers, ruler
- Check of the lot according to the instructions on the inspection plan
- Check of cutting angle according to attachment 2

Tolerance for the dimension of the total length of an instrument lot: +/- 5 mm

**Scissors, which differentiate from each other too greatly in total length within one lot, are to be sorted out and rejected!**

- In order to guarantee the exchangeability of every instrument of an article, the shape, curvature, surface finish, thickness, break of edges, blade and blade thickness must be identical.

**1.4** Visual inspection:

- There must be no visible stains on the scissors (e.g. water spots, rust film, discoloration).
- The end of the screw (end of thread) must not be visible, i.e. the back side of the scissors must be planar. The end of the screw must never project out of the scissors (sharp, danger of injury).
- The surfaces must be free of pores, cracks, grooves, cinder residue, acidic fats and residue of grinding and polishing agents.
- The bolt head must be plane or semicircular, depending on the model.
- The slit of the screw must be straight and clean (no damage, e.g. from a screwdriver when screwing in a screw).
- Right and left part of the scissors must be uniform and match each other optically.
- Rings must be oval and perfectly polished, i.e. the raw material must have been uniformly removed.
- Edges in the joint must be broken roundly toward the shanks.
- The break of edges at the joint for scissors up to 12 cm long must be broken at least 0.2 and 0.3 mm and, for scissors of 13 cm length and longer, at least 0.5 mm, to avoid injuries.
- The screw joint must close completely, i.e. there must not be any large spaces or fringes visible when the scissors are looked at from the side.
- When the scissors are closed, no spaces must be visible between the shanks; the shanks must be parallel and superimposable, even when looked at from the side.
- The counterbore for the screw head must not be too large; i.e. the gap between the diameter of the counterbore and the screw head diameter must not be large.
- When the scissors are open, there must not be a lot of play in the screw joint.
- No numbers may be punched into the shanks.

File name	Revision	written on	by	last changed on	by	Page
PA 04 – Scissors	A	18.10.04	SK	25.04.2014	SK	1 / 13

Example of one of the nopa internal test instructions in accordance with the standards.



## PA 04 – Scissors

nopa<sup>®</sup> instruments

### 1.5 Function test:

- The main function of a pair of scissors is its cutting capability and must be tested (Cutting capability test, see 5.6.1).
- When the scissors are closed, there must be no sharp edges/corners on them.
- In the case of dull scissors, the points at the end of the blades must be rounded.
- In the case of sharp scissors, the points must be symmetric and sharp.
- Scissors must operate well and may only close over the back third of the cutting blade. After this, the scissors must resist; i.e. the front 2/3 put up a low resistance, which brings about the cutting capability.
- The cutting surface must be fine and planar, i.e. it may not have any grooves, nicks or dents.
- No manufacturing residues, such as polishing dust or sand-blasting particles may be on the scissor blade or joint.
- The scissors may not hook during cutting, and no nicks may form on the cutting edge.
- A pair of scissors may not break or bend if used / handled properly.

### 1.6 Cutting capability test:

The cutting capability of the scissors is tested with a cutting test.

Cutting test procedure:

According to DIN 58298 Part 2, test material is to be used according to Table 2. (see attachment)

The scissors are to be cleaned before testing.

To test the cutting capability, 3 uninterrupted cuts over 2/3 of the cutting length of the scissors is cut through the test material, without applying lateral pressure. The test material must be smoothly cut, without tearing.

The test material is to be layered according to Table 2, according to the respective type of scissors.

The tip of the scissors must be checked with Latex, must not get caught.

### 1.7 Evaluation criteria:

1. If the scissors of the first random test are okay, the untested instruments are packaged in bundles of 10 in boxes.
2. Small optical defects, such as scratches, kinks, small dents, water spots, discoloration, etc. do not justify a return.
3. Optical defects, which can't be reworked in the workshop, justify a return.
4. Functional errors justify a return.

**1.8** If the number of faulty instruments should be higher than the acceptance number defined in **AA-02**, the manager of Purchasing / Logistics or the QMB is to be informed. They decide whether a 100% test, special release or rejection of the lot is carried out.

File name	Revision	written on	by	last changed on	by	Page
PA 04 – Scissors	A	18.10.04	SK	25.04.2014	SK	2 / 13



Our test procedures include, among others:

### Model consistency test

Our instruments are checked on the basis of our master samples and the associated technical drawing.

### Hardness test

Just as important as the right choice of raw material is a correct heat treatment during the production process, since the molecular structure and the associated hardness determine, among other things, the **durability and functionality** of the surgical instruments. The hardness of the instrument is tested according to DIN EN ISO 6507-1 or DIN ISO 3738-1.

### Visual inspection

We distinguish between two types of visual inspection. On the one hand, this is performed by the trained eye of our qualified testing and quality assurance personnel and, on the other hand, optics are used with an up to 38-times magnification or microscope. We are thus able to determine all kinds of **defects from surface damage** down to the **smallest cracks** or **corrosion**.

### Boiling test/autoclaving

After the usual **process guided cleaning**, the instruments are placed into a tank with demineralised water, which is then brought to a boil. A boiling test is deemed to have been passed when the instrument **shows no signs of corrosion** after drying. As a further test, the instruments are subjected to a sterilization cycle. In an autoclave with steam and pressurised atmosphere, the instrument undergoes a sterilization cycle. The instruments **must not show any signs of corrosion** after this test either.

### Function Test

**Function** is the priority here: the movement of working parts, locks, and the elasticity are tested. Cutting is checked using scissors, scalpels, and forceps and punches. All these and other functions are performed in accordance with the standard DIN 58298:2010-09.

### Passivation

After the **complete cleaning** of the instruments, they are inserted into a special passivation liquid and passivated, in accordance with a specific process determined by the nature of the instrument, for between 5 to 30 minutes in an ultrasonic bath and then rinsed.

### Marking

As we also offer, in addition to electro-chemical labelling, the possibility of laser labelling, it is an absolute must for us to test the labelling for **legibility, completeness, and cleanliness**. Our instruments only leave our facilities with a standardised and professional labelling.



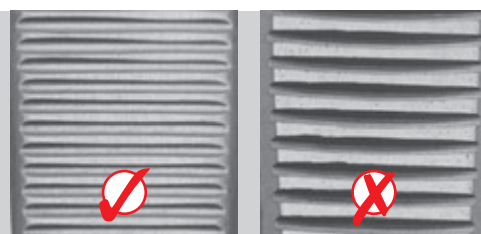
The basis of our quality controls are the **DIN standards for medical instruments** and the **Medical devices directive (93/42/EEC)**. These guidelines and legal foundations have been firmly rooted in all areas of our company for many years.

We have also created our own specific **nopa** test instructions for all our product groups. They define requirements on our products, services and company processes, and provide clarity on their characteristics.

### Grip surfaces on a pair of tweezers

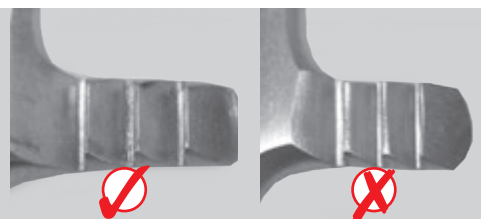
It is important that no sharp edges are present on the grip surfaces of a pair of tweezers.

A proper processing of the grip surfaces is essential.



### Ratches

A ratched must be precisely milled to allow safe working conditions.

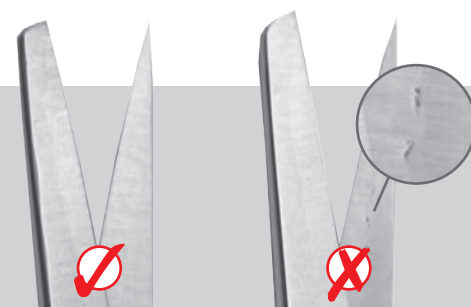


**nopa instruments** checks each instrument so that it meets our quality standards. Negligent processed instruments, compounds with pores or blunt instruments do not pass our strict quality controls.

### Carbide scissors

Pores in the welding of a scissor blade of a pair of tungsten carbide scissors can lead to corrosion and breakage.

**nopa**  
**TUE**



### Working ends of tweezers with groove

To ensure a secure grasp of the tweezers these must be precisely machined and free from burrs.



**nopa** guarantees high product quality.  
The warranty period can, of course, be extended.

— reusable surgical —  
— instruments —

nopa® instruments

nopa instruments GmbH >> Postfach 45 54 >> D-78510 Tuttlingen

Herstellung und Verkauf chirurgischer  
und endoskopischer Instrumente  
Manufacture and Sales of Surgical and  
Endoscopic Instruments

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78532 Tuttlingen / Germany

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Fax +49.7462.9490-90  
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www.nopa.de

## Quality warranty

We provide a quality warranty for our products for a period of **2 years** from the date of delivery.

If a product supplied by us suffers a defect, we will ensure that the defect is rectified within the scope outlined below:

### 1. Scope of protection

This declaration only applies if the product is rendered useless or its usefulness is seriously adversely affected (defect) as a result of a design, production or material flaw, which existed when it was supplied to the customer. It shall not apply in particular if the adverse effect on the usefulness of the product is caused by natural wear and tear, incorrect usage or external effects. This declaration shall also not be applicable if the customer intentionally or due to gross negligence breached statutory or official regulations, in particular the Medical Product Law and the laws and directives specified therein whilst bring the product into circulation, during its storage or during the use of the product.

This declaration does not contain any guarantee of the properties or the durability of the product.

### 2. Claims by the customer on the basis of the declaration

In the event of a justified claim being made on the basis of this declaration we shall, at our own discretion, exclusively rectify the product defect (refinishing) or supply a perfect product. The purchaser cannot derive any further claims or rights from this declaration, in particular no claim for the reimbursement of costs incurred due to the defect and shall also have no claims for compensation for consequential damage. Both the transport of the product from the purchaser to us and the return transport shall be at the risk of the purchaser.

### 3. Period of validity

This declaration shall only be valid for claims received by us on the basis of this declaration within the claim period of **2 years** specified above. This claim period shall end in any event, however, **24 months** after the date of production of the product as specified by the date stamp on the product or as per the entry in the documentation supplied with the product, such as the delivery date, operating manual or device certificate. If defects are reported after the expiry of the claim period or the verifications or documents required by this declaration are not submitted until after the expiry of the claim period, the purchase shall not be entitled to any rights or claims on the basis of this declaration.

page 1 / 2



Deutsche Bank AG Tuttlingen  
(BLZ 653 700 75) Nr. 21 80 750

S.W.I.F.T. - Code: DEUTDE 55 653  
IBAN DE 17 6537 0075 0218 0750 00

Die gelieferte Ware bleibt zur vollständigen  
Bezahlung unser Eigentum

Lieferung ausschließlich nach unseren  
allgemeinen Lieferbedingungen

Erfüllungsort und Gerichtsstand  
ist Tuttlingen

Amtsgericht Tuttlingen HRB 413  
Geschäftsführer: Norbert Pauli u. Erik Hummel





## nopa<sup>®</sup> instruments

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### 4. Defect notification

As soon as the purchaser discovers a defect on the product, he must notify us of it in writing immediately but at the latest three working days after the discovery of the defect. Otherwise he will lose all claims on the basis of this declaration.

### 5. Making claims on the basis of the declaration

To make claims on the basis of this declaration, the following must be submitted or notified to us at the expense and risk of the customer:

- Detailed description of the defect,
- The date of production,
- The invoice, delivery note or other suitable documents to verify the date of production and the date of purchase from us.

### 6. Statute of limitations

If we do not acknowledge properly lodged claims based on this declaration in writing, all claims from this declaration shall become statute-barred six months after the date of the claim, but not before the end of the claim period.

### 7. Applicable law

Material German law shall apply exclusively to this declaration and all claims, rights and obligations resulting from it, excluding the standards of International Private Law and also excluding UN-Convention on Contracts for the International Sale of Goods (CISG).

\_\_\_\_\_  
Date, Company

THIS IS A TRANSLATION OF THE ORIGINAL TEXT IN GERMAN AND IS THEREFORE NOT LEGALLY BINDING AT ANY TIME.  
THE GERMAN ORIGINAL TEXT ALONE IS LEGALLY BINDING.

page 2 / 2

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**nopa instruments** uses every opportunity to get and stay in touch with its customers and prospective customers. For this reason, we regularly attend exhibitions and congresses around the world.



Medica 2015

These include, among others:

- >> **MEDICA**, Düsseldorf
- >> **Arab Health**, Dubai
- >> **Africa Health**, South Africa
- >> **Medic East Africa**, Kenya
- >> **Medic West Africa**, Nigeria
- >> **Hospitalar**, Sao Paulo
- >> **Medical Fair**, South-East Asia
- >> **Zdravookhraneniye**, Russia
- >> **Exposanita**, Italy
- >> **Belarus Medica**, Minsk



Our customer service team is always pleased to be there for you. We speak several languages, including:  
**Deutsch, English, Français, Español, Italiano and русский.**



We are also always happy to hear the suggestions of our customers. That is why we are particularly proud to receive positive feedback on our performance and our quality from various countries around the world.

... find more feedback from our customers on our homepage at [www.nopa.de](http://www.nopa.de)

## INTERNATIONAL RESPONSE



### India

"We purchased a laparoscopy set from your esteem organization, Nopa Germany in September 1998, since then, we are very much satisfied with the performance."

### Egypt

"Thank you very much for your great assistance and additions you made to us. I appreciate doing such a great job in such a short and precious time."

### Australia

"Wow, just installed the new containers and the first time I am seeing them and wanted to comment that they are quite impressive especially the Locking side and more attractive."

### Italy

„Grazie nopa. Sei super brava. A presto. un caro saluto“

### Paraguay

"buenos días: la prueba fue excelente pero estaba esperando tener la carta o la respuesta oficial. Solo dos pasaron la prueba de esterilización y nopa fue uno de ellos es lo que me comentan así que te estaré informando supuestamente hoy tendría novedades sobre eso. Saludos cordiales."

### Singapore

"Wow..... your service level is really fantastic. Beyond words. You have just saved us!! Thank you so very much. Lots of hugs and kisses."

### USA

"I am so very happy with the quality of your products. So are my customer. I am very close to distributing a catalogue featuring the instruments along with pictures. I have many distributors across the country waiting for its release. My customer stresses good quality and I try to provide an ease with ordering. With this in mind, I want to stress the importance of the etching on the instruments. This is very important to us."

### South Africa

"Vielen Dank. This looks like a good amount of items, I think we can ship those. By the way, we got the instruments and catalogues from you guys. It is beautiful!! The instruments seems very high quality and well worked off, we are very excited to do more business with you!!"



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