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ЗНАКОМСТВО С КОМПАНИЕЙ

Головной офис компании **nopa instruments** находится в Туттлингене (Германия), всемирном центре медицинских технологий.

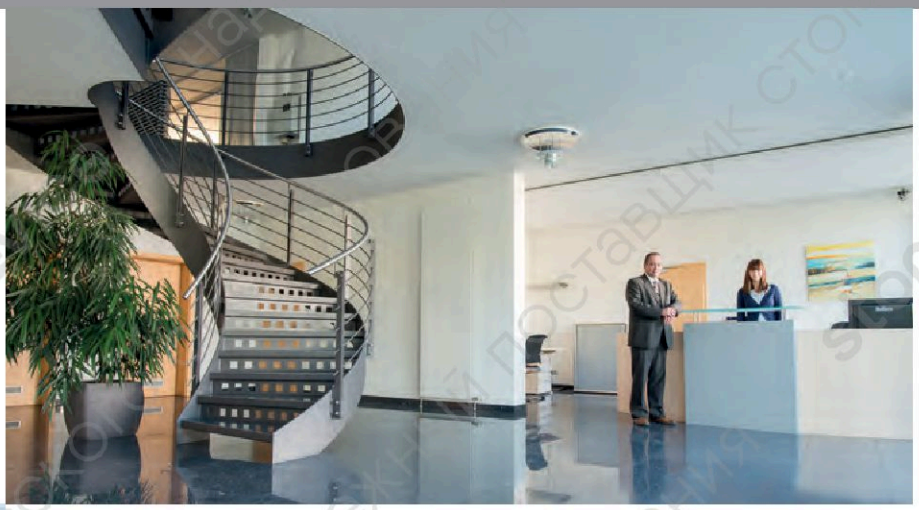


- >> Компания основана в 1982 году
- >> Учредители компании **Но**рберт **Па**ули и Моника Паули
- >> Десятилетия опыта в области хирургических и эндоскопических инструментов, а также стерилизационных контейнеров
- >> Одна из первых компаний в секторе, сертифицированная с 1995 года согласно международным стандартам и нормам

>>

ИНФОРМАЦИЯ О КОМПАНИИ

QUALITY PLUS



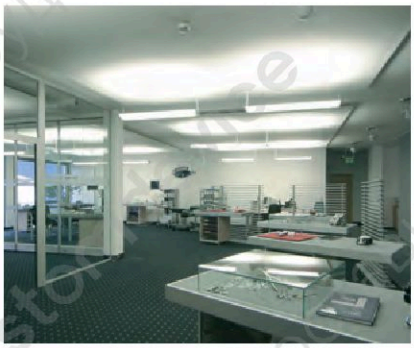


Торгово-промышленная палата
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(ид. № 36325694)

Ремесленная палата города Констанц
(ид. № 31659)

Окружной суд города Штутгарт
(регистрационный № HRB 450413)



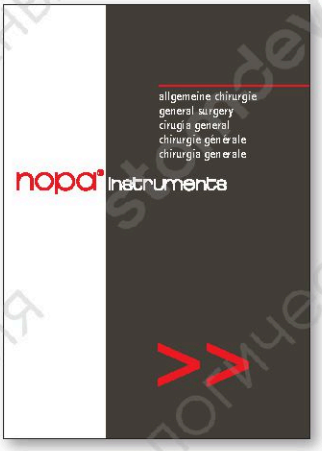


Мы являемся **членами различных комитетов** и участвуем в различных международных исследованиях:

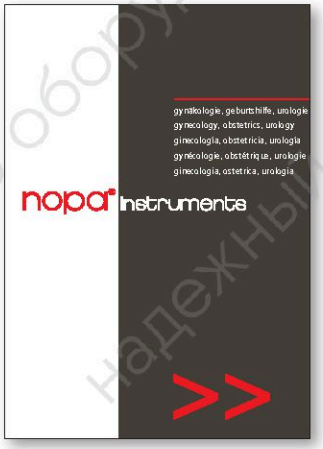
>> Стерилизация и очистка инструментов
>> Стерилизация инструментов
>> Процесс аттестации

АССОРТИМЕНТ ПРОДУКЦИИ И КАТАЛОГИ

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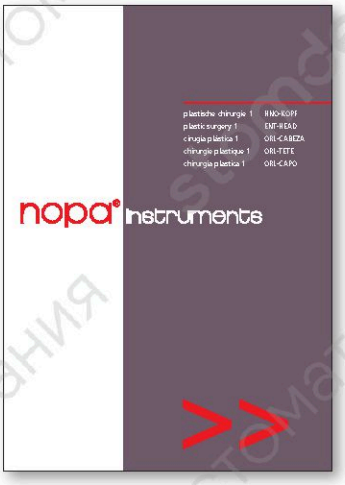
A-K общая хирургия
представлена на 664 страницах



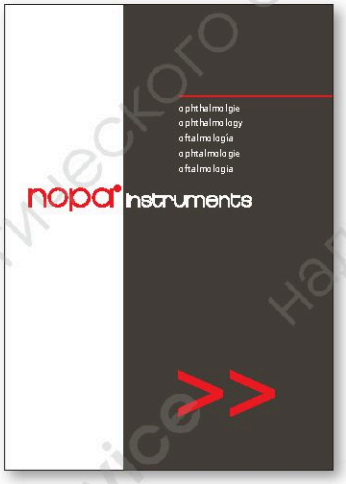
KB-KC гинекология, акушерство и урология, представлены на 574 страницах



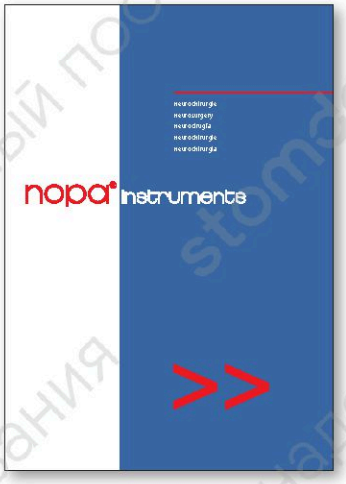
KK сердечно-сосудистая хирургия представлена на 380 страницах



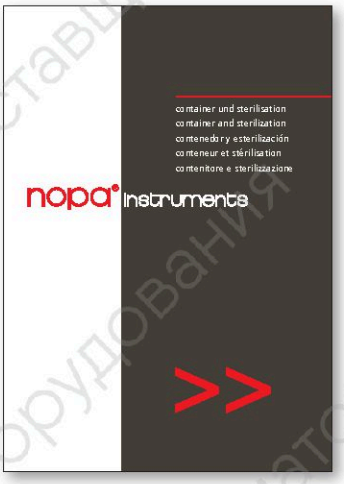
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ENT-HEAD
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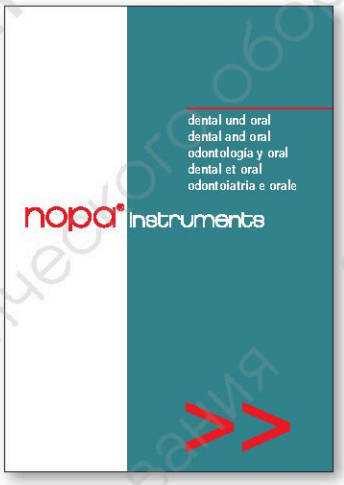
KP офтальмология
представлена на 238 страницах



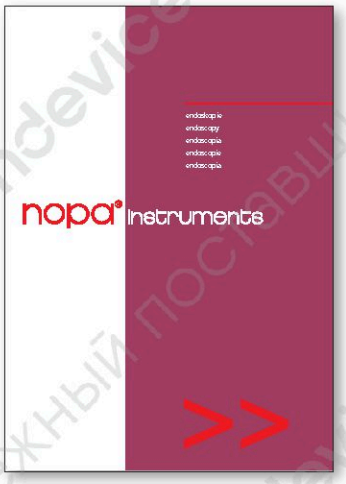
KS нейрохирургия
представлена на 201 страницах



KYE контейнеры и стерилизация
представлены на 136 страницах



P стоматология и ротовая полость
представлены на 404 страницах



X эндоскопия
представлена на 266 страницах

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СЕРТИФИКАЦИЯ CE



Certificate

mdc medical device certification GmbH
certifies that

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

for the scope

development and design, production and distribution of surgical, dental and HF instruments with accessories, endoscopy materials, needles, sterilization containers

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2015-06-25
Valid until	2018-06-24
Registration no.	D1121700019
Report no.	P15-00527-44480
Stuttgart	2015-06-25

Head of Certification Body

mdc

DAkkS



EC Certificate

edical device certification GmbH
Notified Body 0483
herewith certifies that

pa instruments
nstruments Medizintechnik GmbH
Weilatten 7 - 9
78532 Tuttlingen
Germany

for the scope

n and irrigation cannulae (10-566), Klasse IIa;
py forceps with HF connection (11-502), class IIb

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 – excluding Section 4
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.

Valid from	2015-06-25
Valid until	2020-06-24
Registration no.	D1121700020
Report no.	P15-00527-44484
Stuttgart	2015-06-25

Head of Certification Body

mdc

nopa instruments имеет систему управления качеством в соответствии со стандартом ISO 13485, основанном на директиве 93/42/ЕЭС от 14.06.1993 г. для медицинских инструментов.

Все наши сертификаты доступны для загрузки на нашем веб-сайте

the nopa philosophy
CERTIFICATION
Quality Plus

Пожалуйста, отправьте запрос для получения декларации о соответствии нормам ЕС

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 Fertigungsdatum 01.01.2010
bis Fertigungsdatum 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/EWG	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

tgruppenliste
duct group list

Produktgruppen-Bezeichnung *Product group description*	UMDNS-Nr.	Risikoklasse	Regel
Klemmen / *Hemostats*	10851	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*	13708	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*	17533	1	6
DE/CA39/648/67	KD	Darm, Magen, Mastdarm / *Intestines, Stomach, Rectum*	13865	1	6
DE/CA39/648/32	KI	Mammaplastik / *Mammaplasty*	13373	1	6
DE/CA39/648/11-12	KK	Herz, Thorax / *Cardio vascular*	10838	1	6
DE/CA39/648/76-77	KL	Mund, Zunge, Tonsillen/ *Oral instruments, Tonsils*	15872	1	6
DE/CA39/648/82	KM	Otologie / *Otology*	13662	1	6
DE/CA39/648/83	KO	Rhinologie / *Rhinology*	13632	1	6
DE/CA39/648/72	KS	Clips/clip	10898	1	6
DE/CA39/648/32	KS	Säge/saw	13448	1	6
DE/CA39/648/30	KS	Zange / *Forceps*	11774	1	6
DE/CA39/648/85	KS	Haken / *Hook*	12028	1	6
DE/CA39/648/13	KS	Zange Fixation / *Forceps fixation*	11781	1	6
DE/CA39/648/25	KS	Mikrochirurgieinstrument / *Micro surgery instrument*	15621	1	6
DE/CA39/648/64	KS	Spreitzer / *Spreader*	13707	1	6
DE/CA39/648/89	KS	Stanze / *Punch*	13228	1	6
DE/CA39/648/94	KS	Elevatorium / *Elevator*	11507	1	6
DE/CA39/648/95	KU	Verschiedenes / *Various items*	15561	1	6

Stand 22.06.2015

Dateiname	Revision	erstellt am	von:	zuletzt geändert am	von:	Seite
FB Produktgruppenliste Klasse I.doc	A	21.03.2010	Kappeler	09.04.2013		1 von 1

ИССЛЕДОВАНИЕ / АНАЛИЗ ФРАЙБУРГСКОГО УНИВЕРСИТЕТА

Исследование **Клиники фрайбургского университета**:
Сравнение инструментов nopa с инструментами, используемыми в клинике

UNIVERSITÄTS KLINIKUM FREIBURG
STUDIENZENTRUM

MPE – nopa instruments Medizintechnik GmbH

Title of the study: Market preference analysis (MPE-nopa) Evaluation of different instruments from the company nopa instruments Medizintechnik GmbH
Client: nopa instruments, Medizintechnik GmbH, Weilatten 7-9, 78532 Tuttlingen
Test product(s): 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
Objective of the study: Evaluation of handling during surgery / application of the aforementioned surgical products
Study design: Survey of OP personnel by means of a questionnaire **Case number (planned and analysed):** N=25 (25 different applications in the study period)
Study procedure: Survey of OP personnel by means of a questionnaire with regard to the evaluation of different instruments from the company nopa-instruments **Study conducted by:** University Clinic Freiburg, Study Centre
Date of the beginning of the study: 01.04.2013 **Date of completion of the study:** 31.12.2013
Summary of the results: 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
Conclusions: 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

Concluding report MPE nopa instruments, Version 01, 10.02.2014 Page 1 of 2

UNIVERSITÄTS KLINIKUM FREIBURG
STUDIENZENTRUM

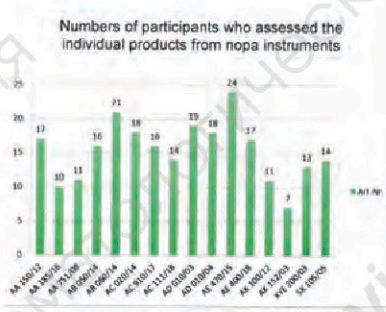


Diagram 1



Diagram 2

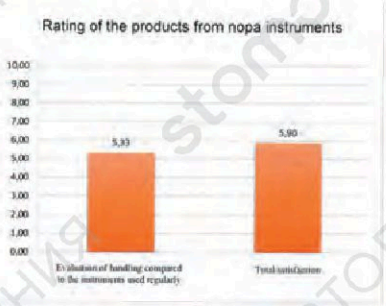


Diagram 3

Authors:

Birgit Grotejohann Project coordinator Study Centre	Signature	Freiburg 26.02.2014 Place, date
Julia Maurer Project assistant Study Centre	Signature	Freiburg 26.02.2014 Place, date
Erik Hummel Managing Director	Signature	Tuttlingen 28.02.2014 Place, date

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КОРПОРАТИВНЫЕ БРЕНДЫ

nopa instruments

nopa TUC

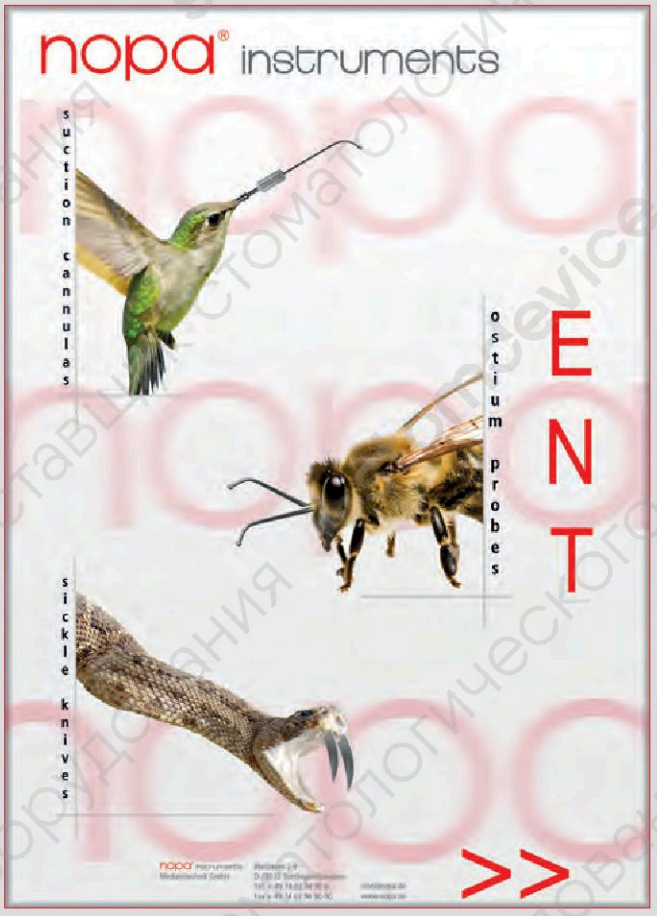
SUPER CUT TUC

SUPER CUT

ATRAUMA nopa

nopa

ПОСТЕРЫ



Постер ENT



Постер стерилизация



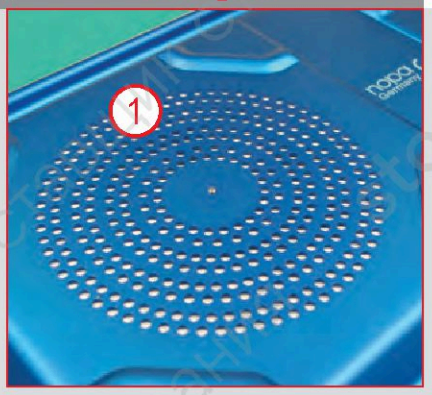
Предлагаются также постеры **nopa instruments** в формате 50 x 70 см для ваших выставочных стендов..

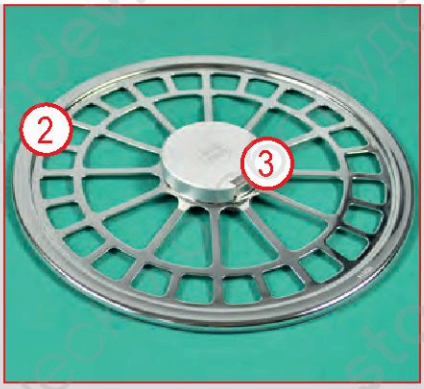
Постеры инструментов

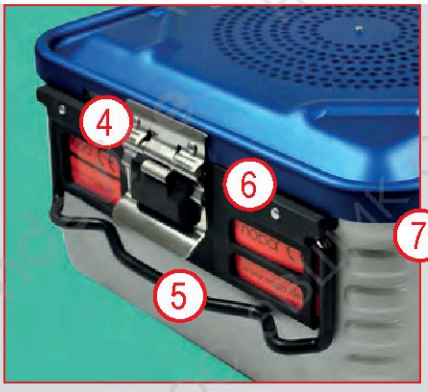


Аттестационный сертификат приведен на стр. 14

Дизайн **nopa**







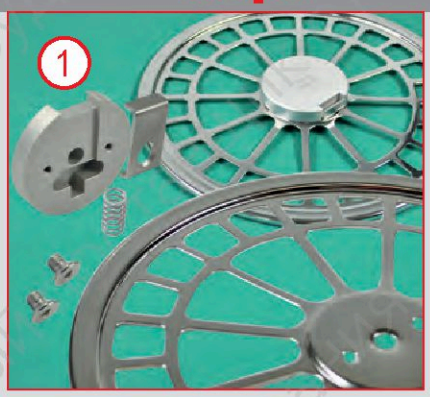
1. Круговая перфорация на крышке
2. Держатель фильтра проверенной конструкции
3. Собственное защищенное запорное устройство
4. Специальный замок **nopa**
5. Эргономичные ручки с силиконовым покрытием
6. Эффектная сплошная черная передняя панель
7. Защита углов

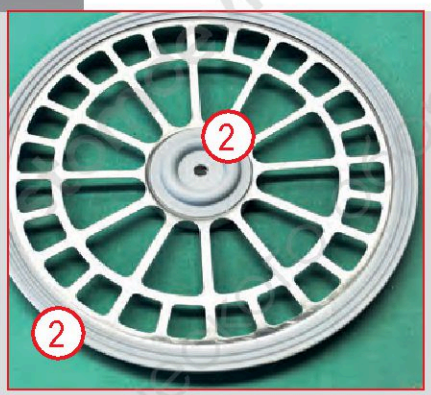


По запросу мы нанесем на контейнер название или логотип с помощью лазера.

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STERILIZATION
Quality Plus

Качество **nopa**

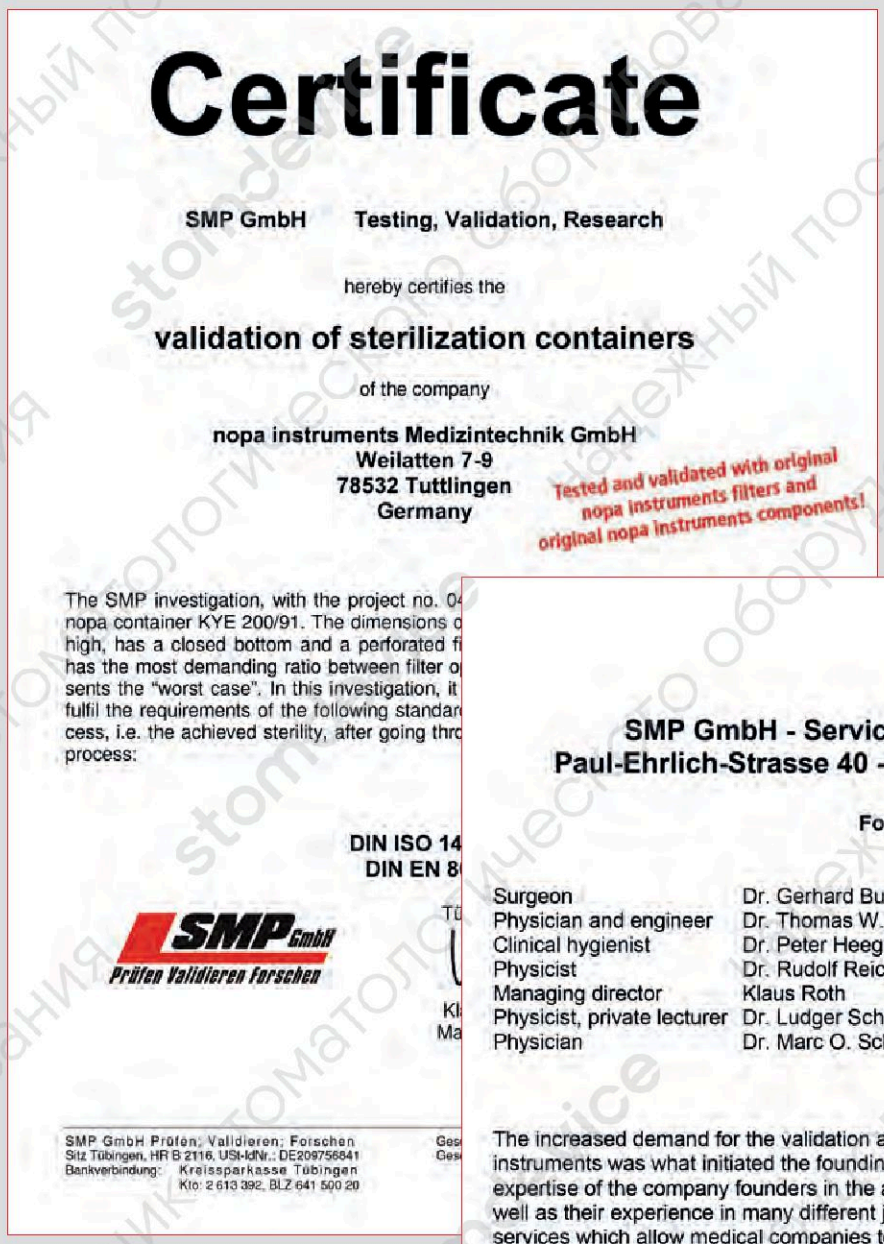






1. Сборка держателя фильтра
2. Приклеивание внутреннего и внешнего колец к держателю фильтра
3. Приклеивание силиконового уплотнения со внутренней стороны крышки контейнера

Выполнено и проверено нашей высококвалифицированной командой



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. 0
nopa container KYE 200/91. The dimensions o
high, has a closed bottom and a perforated fi
has the most demanding ratio between filter o
sents the "worst case". In this investigation, it
fulfil the requirements of the following standar
cess, i.e. the achieved sterility, after going thro
process:

DIN ISO 14
DIN EN 8

SMP Prüfen Validieren Forschen

SMP GmbH Prüfen; Validieren; Forschen
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Bankverbindung: Kreissparkasse Tübingen
Kto: 2 613 392, BLZ 641 500 20

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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.

the nopa philosophy
VALIDATION
Quality Plus

FROM THE FIELD

STERILISATION

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

Steam Sterilisation of Reusable Surgical Instruments

Effectiveness Limits

I. Haas, H. Henn, U. Junghanß, K. Kabel, D. Tath, 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.

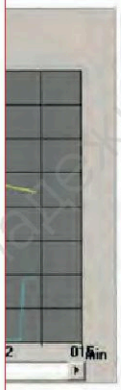
In our tests we used the following types of biological indicators:

- Spore strips of *Geobacillus stearothermophilus* ATCC 7953 with an average baseline microbial count of 1.0×10^6 cfu/germ carrier (filter paper) and a D-value of 1.5 min at 121 °C.
- Spore suspensions of *Geobacillus stearothermophilus* ATCC 7953 with 2.6×10^8 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 µl 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



el, 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 µl 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

hread represented a worst-case feature.

and DIN EN 61010-1/2-041. The chamber capacity is 9.3 l.

A test steriliser manufactured by the firm Lautenschläger (Protocert 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-

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 word-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 mod-

Весь документ (5 страниц) доступен для загрузки на нашем веб-сайте.

Анализ для определения времени стерилизации. Выполнен рабочей группой «Подготовка хирургического инструментария».

nopa instruments была участником этой рабочей группы.

ИСПОЛЬЗУЕМЫЕ МАТЕРИАЛЫ

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 DIN EN 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

обзор используемых высококачественных материалов

the nopa philosophy
MATERIAL
Quality Plus

opa® instruments

	Probes / Trocars / Suction Tubes	Chisels / Bone Curettes	Mallets	Needleholder	Handle (hollow)	Handle (solid)
	AL, AO, XK, 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					

i	Div	DIN10088-1/AISI F899
ax		1.4024 / 410
ax		1.4021 / 420A
ax		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
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(BLZ 342 500 00) Konto 525 3299

Ihre Nachricht vom | Mein Zeichen O/St. | 42655 Solingen 06.12.11

analysis and hardness measurement of two instruments (A.-Nr.5075)

*he OES-analysis (optical emission sprectroscopy)**

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
eel-grade	~ AISI 420	~ AISI 420
hardness in HV10 ~ **HRC**	529 – 542 ~ 51,0 – 51,8	434 – 437 ~ 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.

Oliver Stoll

Анализ материалов ножниц Metzenbaum и зажимов Doyen.

ПРОИЗВОДСТВЕННЫЙ ПРОЦЕСС

Закупка и контроль заготовок

V

Проверка заготовок и сырья

V

Сверление и фрезеровка

V

Подгонка и соединение частей

V

Закалка и улучшение

V

Проверка твердости

V

Шлифовка и полировка

V

Очистка

V

Нанесение номера партии

V

Завершающий осмотр

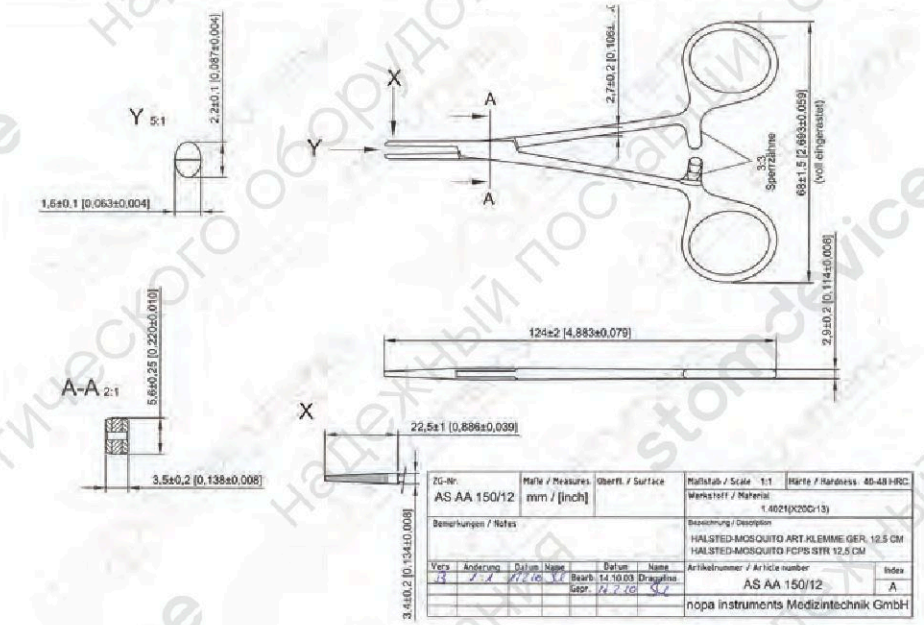
V

Проверка пройдена

V

Складирование проверенных инструментов

Технический чертеж



«От сырья до готового инструмента»

Процесс изготовления хирургического зажима



ФОТОГРАФИИ ИЗ НАШЕГО ИСПЫТАТЕЛЬНОГО ЦЕНТРА

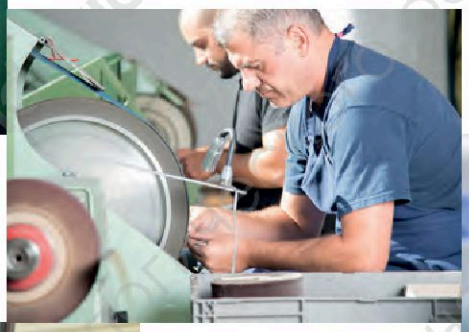


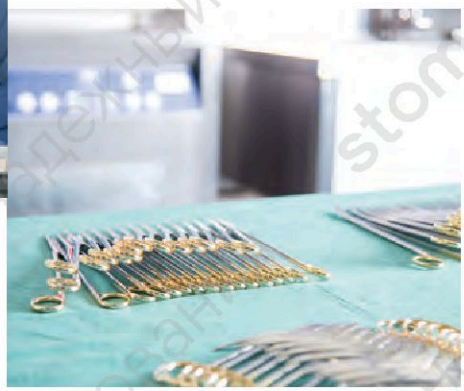
Испытание твердосплавных вставок в держателях игл





Обработка поверхности





Очистка и пассивация инструментов



Испытание твердости





Образцы заготовок, готовые инструменты и чертежи для идентификации и испытания инструментов

PA 04 – Scissors

nopa instruments

1.0 Description of the test method

1.1 Samples are taken according to **AA-07.**
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

Образец внутренних инструкций для испытаний компании nopa в соответствии со стандартами.

PA 04 – Scissors

nopa 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.

the nopa philosophy
TESTING
Quality Plus

ПРОЦЕДУРЫ ИСПЫТАНИЙ

Наши процедуры испытаний включают помимо прочего:

Испытание на соответствие модели

Наши инструменты проверяются с помощью шаблонов и соответствующих технических чертежей.

Испытание жесткости

Как и правильный выбор сырья, во время производственного процесса важна надлежащая температурная обработка, поскольку молекулярная структура и соответствующая жесткость среди прочего определяют долговечность и функциональность хирургических инструментов. Жесткость инструмента испытывается согласно DIN EN ISO 6507-1 или DIN ISO 3738-1.

Внешний осмотр

Мы различаем два вида внешнего осмотра. Во-первых, он выполняется квалифицированным персоналом, проводящим испытания и контроль качества, и, во-вторых, используется оптика с увеличением до 38 или микроскоп. Таким образом, мы можем найти все виды **дефектов от повреждения поверхности** до **мельчайших трещин** или **коррозии**.

Испытание кипячением

После обычной **очистки** инструменты помещаются в емкость с деминерализованной водой, которая затем доводится до кипения. Испытание кипячением необходимо для того, чтобы убедиться в том, что после сушки инструменты **не имеют признаков коррозии**. Следующим испытанием является выполнение цикла стерилизации инструментов. В автоклаве, наполненном паром под давлением, инструменты проходят цикл стерилизации. Инструменты **не должны иметь никаких признаков коррозии** и после этого испытания.

Функциональные испытания

Испытывается движение подвижных деталей, замков, а также эластичность. Проверяется режущая способность ножниц, скальпелей, зажимов и перфораторов. Все эти и другие функции выполняются в соответствии со стандартом DIN 58298:2010-09.

Пассивация

После **полной очистки** инструменты помещаются в специальную пассивирующую жидкость и пассивируются в соответствии со специальным процессом, определяемым типом инструмента в течение 5-30 минут в ультразвуковой ванне, после чего промываются.

Маркировка

Поскольку помимо маркировки электрохимическим способом мы предлагаем возможность лазерной маркировки, для нас является обязательным тестирование на **читаемость, полноту и четкость**. Наши инструменты покидают производство со стандартизированной и профессиональной маркировкой.

>>



Основой нашего контроля качества являются **стандарты DIN для медицинских инструментов** и **Директива о медицинских устройствах (93/42/ЕЭС)**. Эти нормативы и законодательная база за много лет надежно закреплены во всех сферах деятельности нашей компании.

Мы также разработали свои собственные особые инструкции для испытаний всех групп продуктов компании **nopa**. Они определяют требования к нашим продуктам, услугам и процессам компании и обеспечивают точность их характеристик.

Поверхности захвата на пинцете

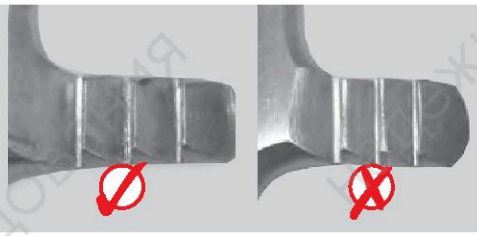
Важно, чтобы на поверхностях захвата пинцета не было острых краев.

Важна правильная обработка поверхности захвата.



Кремальеры

Кремальеры должны быть изготовлены с высокой точностью, чтобы обеспечивать безопасные условия труда.

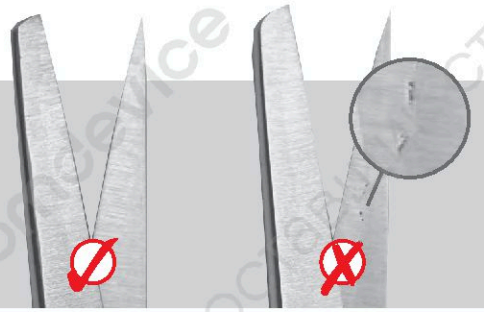


Компания **nopa instruments** проверяет каждый инструмент на соответствие стандартам качества.

Твердосплавные ножницы

Поры в сварном шве лезвия вольфрамовых твердосплавных ножниц могут вызвать коррозию и разрушение.

nopa TUC

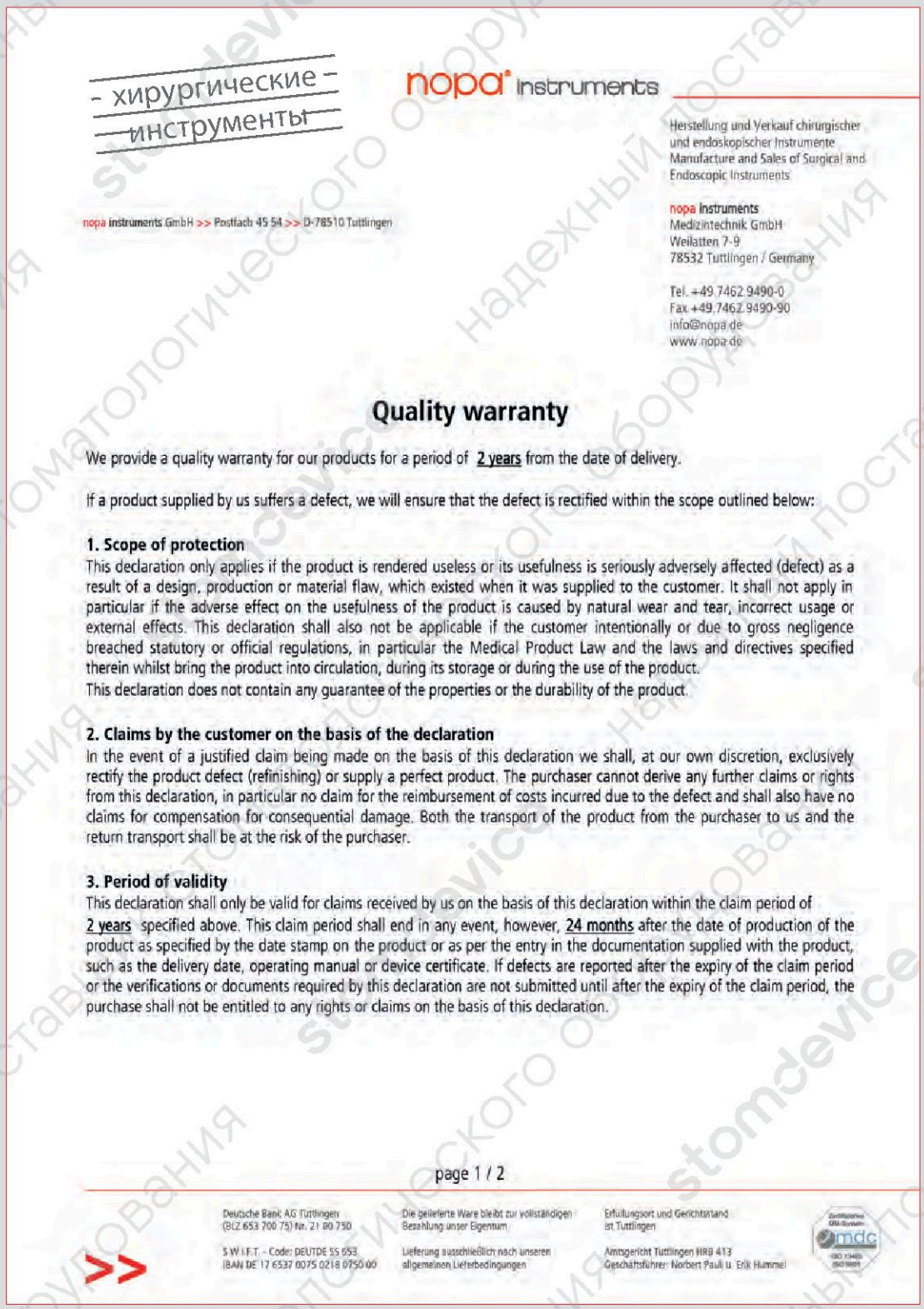


Рабочие концы пинцетов с углублениями

Для обеспечения надежного захвата пинцета он должен быть изготовлен точно и не иметь неровностей.



Компания **nopa** гарантирует высокое качество продукции.
Гарантийный срок, разумеется, может быть продлен.



- хирургические -
инструменты

nopa instruments

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

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info@nopa.de
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.

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

S W I F T - Code: DEUTDE 5S 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 instruments

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

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

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

Tel. +49.7462.9490-0
Fax +49.7462.9490-90
info@nopa.de
www.nopa.de

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 statue-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.

Deutsche Bank AG Tuttlingen
(BLZ 653 700 75) Nr. 21 80 750
S.W.I.F.T. - Code: DEUTDE 55 653
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Компания **nopa instruments** использует каждую возможность поддержания контактов с существующими и будущими клиентами. По этой причине мы регулярно посещаем выставки и конгрессы по всему миру.



Medica 2015

Они, среди прочего, включают:

>> **MEDICA,** Дюссельдорф
>> **Arab Health,** Дубай
>> **Africa Health**, Южная Африка
>> **Medic East Africa,** Кения
>> **Medic West Africa,** Нигерия
>> **Hospitalar,** Сан-Паулу
>> **Medical Fair,** Юго-восточная Азия
>> **Здравоохранение,** Россия
>> **Exposanita**, Италия
>> **BelarusMedica**, Минск

>>

Наша команда службы работы с покупателями всегда рада вам помочь. Мы говорим на нескольких языках, включая: немецкий, английский, французский, испанский, итальянский и русский.



Мы также всегда рады выслушать предложения наших клиентов. Вот почему мы особенно гордимся положительными отзывами о результатах нашей работы и нашем качестве из разных стран мира.

... другие отзывы от наших клиентов приведены на нашем веб-сайте по адресу www.nopa.de

МЕЖДУНАРОДНАЯ РЕАКЦИЯ

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"

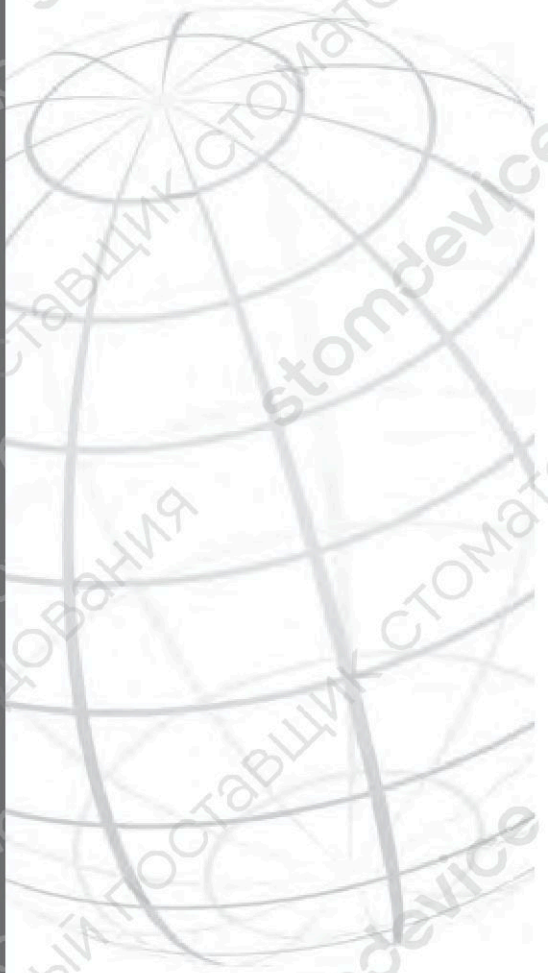
Paraguay
"buenos días: la prueba fue excelente pero estaba esperando tener la carta o la respuesta oficial. Solo dos pasaron la prueba de esterilización y nopa fue uno de ellos es lo que me comentan así que te estaré informando supuestamente hoy tendría novedades sobre eso. Saludos cordiales."

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 qualitiy 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 exited to do more business with you!!"

stomdevice



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Manufacture and sale of surgical and endoscopic instruments.

https://stomdevice.ru - стоматологическое и зуботехническое оборудование с доставкой по России и СНГ