

To whom it may concern:

Baar, 22 March 2022

### LETTER OF AUTHORIZATION

Smith & Nephew Orthopaedics AG, with offices in Oberneuhofstrasse 10 6340 Baar, Switzerland VAT number CHE 107345392 bank account BIC DEUTCHZZ at DeutscheBankAG. represented by Bartłomiej Zaręba in quality of Business Unit Manager.

As manufacturer of medical devices (hip and knee prostheses, trauma and endoscopy products) hereby confirm that our exclusive distributor for Lithuania is the company

OSTECA, UAB, with offices in Danes str. 47., Klaipeda – Lithuania, registration number 300871049, VAT no. LT100003238211, represented by Mr Arvydas Klovas in quality of General Director.

  
Smith & Nephew Orthopaedics AG  
Oberneuhofstrasse 10D  
6340 Baar Switzerland

**SMITH&NEPHEW**  
Name: Bartłomiej Zaręba  
Position: Business Unit Manager

**OSTECA UAB**  
Name: Arvydas Klovas  
Position: General Director

This authorization is valid for one year beginning with the signing date.

Smith&Nephew Orthopaedics AG  
Oberneuhofstr. 10D  
6340 Baar  
Šveicarija

T +41 79 720 73 11  
[www.smith-nephew.com](http://www.smith-nephew.com)

Tam kam svarbu:

Kovo 22 d., 2022 m., Baar

## ĮGALIOJIMAS

SMITH & NEPHEW Orthopaedics AG, kurios adresas yra Oberneuhofstrasse 10, 6340 Baar, Šveicarija, PVM kodas CHE 107345392, CH7187801001005464001 SWIFT kodas DEUTCHZZ DeutscheBank AG, atstovaujama verslo padalinio vadovo Bartlomiej Zareba

kaip medicininių prietaisų (klubo ir kelio endoprotezų, traumatologinių ir endoskopinių produktų) gamintojas

tokiu būdu patvirtina, kad išskirtinis distributorius Lietuvoje yra kompanija

UAB OSTECA, kurios adresas yra Danės g. 47, Klaipėda, Lietuva, registracijos numeris 300871049, PVM kodas LT100003238211, atstovaujama generalinio direktoriaus Arvydo Klovo.

/Parašas/

Smith&Nephew  
Vardas: Bartlomiej Zareba  
Pareigos: Verslo padalinio vadovas

Osteca, UAB  
Vardas: Arvydas Klovas  
Pareigos: Generalinis direktorius

Šis įgaliojimas galioja vienerius metus, nuo jo pasirašymo datos.



## EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** CE 506114  
**Issued To:** **Smith & Nephew Inc.**  
**Endoscopy Division**  
**150 Minuteman Road**  
**Andover**  
**Massachusetts**  
**01810-1031**  
**USA**

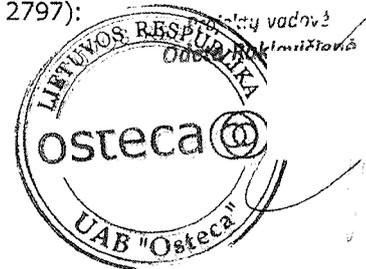
In respect of:

**Design, development and manufacture of absorbable and non-absorbable orthopedic implants, phalangeal and metatarsophalangeal joint repair systems, absorbable matrices to support bone and cartilage, high frequency surgical equipment, sterile tube sets, surgical instruments, battery packs and housings for active handpieces, and related accessories for arthroscopy and laparoscopy minimally invasive and reconstructive surgery areas.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices



First Issued: **2006-06-30**

Date: **2020-02-20**

Expiry Date: **2024-05-26**

...making excellence a habit™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Sertifikatas

Vertimas iš anglų kalbos

Pilnas kokybės užtikrinimas

Direktyvos 93/42/EEC medicininėms priemonėms, Priedas II, išskyrus 4 dalis

Nr. CE 506114

suteiktas:

Smith&Nephew Inc.  
Endoscopy Division  
150 Minuteman Road  
Andover  
Massachusetts  
01810-1031  
JAV

Įskaitant:

Dizainą, vystymą ir gamybą besirezorbuojančių ir nesirezorbuojančių ortopedinių implantų, falanginių ir metatarsofalanginių sąnarių rekonstrukcinėms sistemoms, besirezorbuojančioms matricoms kaulų ir kremzlių rekonstrukcijoms, aukšto dažnio chirurginę įrangą, sterilių vamzdelių rinkinius, chirurginius instrumentus, aktyvių jėgos instrumentų baterijų rinkinius ir dėklus, ir susijusius priedus artroskopijai ir laparoskopijai minimalios invazijos ir rekonstrukcinės chirurgijos sritims.

remiantis kokybės užtikrinimo sistemos patikrinimu, pagal Tarybos Direktyvos 93/42/EEC, Priedo II išskyrus dalį. Kokybės užtikrinimo sistema atitinka direktyvos reikalavimus. Tam kad patiekti rinkoje III klasės produktus pagal Priedo II 4 dalį sertifikatas yra reikalaujamas.

Notifikavimo objekto aukščiau minėtai Direktyvai (Notifikavimo objekto numeris 2797) BSI vardu:

Gary E Slack, vyresnysis vice prezidentas medicininiam prietaisams

Projekto vadovė  
Odetta Rakle

Pirmas leidimas: 2006 birželio 30 d.

Data: 2020 vasario 20 d.

Galioja iki: 2024 gegužės 26 d.



Smith&Nephew GmbH  
Concorde Business Park 1/C/3  
2320 Schwechat  
Austria  
T 43 (0) 1 707 91 02  
F 43 (0) 1 707 91 01  
www.smith-nephew.com

\* We are smith&nephew

## Training certificate

We hereby certify that

**Mrs. Odeta Rakleviciene**

successfully passed the training program of our endoscopy products.

She is trained, can install our products and is able to provide service of Smith & Nephew products.



Vyř. vadybnikė  
Odeta Raľ

2015-08-12

Smith & Nephew GmbH

Business Manager Endoscopy AT & EE  
er, M.Sc.

Smith&Nephew GmbH  
Concorde Business Park 1/C/3  
2320 Schwechat  
Austria

T 43 0 1 707 91 02  
F 43 0 1 707 91 01  
[www.smith-nephew.com](http://www.smith-nephew.com)

## APMOKYMŲ SERTIFIKATAS

Šiuo patvirtiname, kad

**Odeta Raklevičienė**

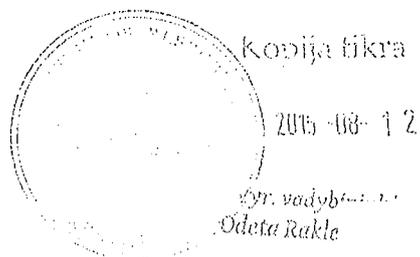
sėkmingai išklausė endoskopinių produktų apmokymo programą.

Ji yra apmokyta, gali instaliuoti mūsų produktus ir teikti Smith&Nephew produktų remonto paslaugas.

Smith&Nephew GmbH

Friedrich Richter Endoscopy AT&EE

/parašas/



Vertimas tikras: vertė Elena Solveiga Rimeikienė, UAB "Fokaja", Liepų g. 16, LT-92114 Klaipėda, Lietuva.  
Vertėjo atsakomybė pagal LR BK 235str. man žinoma.



Vertimas iš anglų kalbos

Smith & Nephew GmbH  
Concorde Business Park C3  
2320 Schwechat  
Austria

T 43 (0) 1 707 91 02  
F 43 (0) 1 707 91 01  
www.smith-nephew.com

 We are smith&nephew

OSTECA, UAB  
Alytaus str. 18,  
Klaipeda  
LITHUANIA

Schwechat, December 30th 2009

TO WHOM IT MAY CONCERN

### WARRANTY REPAIR DECLARATION

This is to certify that Smith&Nephew will provide warranty repair service for all products sold by Osteca, UAB, in Lithuanian market.

Smith & Nephew GmbH

  
Smith & Nephew GmbH  
Concorde Business Park C3

  
Friedrich  
Business Manager Endoscopy Austria & Eastern Europe

December 30<sup>th</sup> 2009



Kopija tikra

yr. vadybininke  
Ijeta Rak' ...

2015-12-30

Osteca, UAB  
Alytaus g. 18,  
Klaipėda  
Lietuva

Schwechat, 2010 m. gruodžio mėn. 30 d

Visiems, ką tai galėtų dominti

## GARANTINIO REMONTO DEKLARACIJA

Šiuo patvirtiname, kad Smith&Nephew teiks visų UAB Osteca parduotų Lietuvos rinkoje produktų garantinio remonto paslaugas.

Smith & Nephew GmbH

Friedrich G.Richter, MSc  
Endoskopijos padalinio vadovas Austrijai ir Rytų Europos šalims  
/parašas/  
/spaudas/

2009 gruodžio 30d.



Vertimas tikras: vertė Elena Solveiga Rimeikienė, UAB Fokaja, Alytaus g. 16, LT-92114 Klaipėda, Lietuva.  
Vertėjo atsakomybė pagal LR BK 235str. man žinoma

LIETUVOS RESPUBLIKA  
UAB FOKAJA  
KRETINGA

U v

# PRO-MED INSTRUMENTE GMBH

CHIRURGISCHE INSTRUMENTE  
MEDIZINISCHE GERÄTE

SURGICAL INSTRUMENTS  
MEDICAL EQUIPMENT

INSTRUMENTS CHIRURGICAUX  
MATÉRIEL MÉDICO-CHIRURGICAL

PRO-MED GmbH · Gänsäcker 9 · D-78532 Tuttlingen

For Presentation to the Competent  
Authorities in Lithuania

Tuttlingen, 22/08/2013

## Letter of Authority

We hereby certify that :

OSTECA, UAB  
Alytaus g. 18  
LI - 92307 Klaipėda  
Lithuania

are authorised and official distributor for

M/S **PRO-MED** Instrumente GmbH, D-78532 Tuttlingen

in Lithuania.

M/S. OSTECA UAB, are fully authorized to import, distribute / market, sell, advertise and service our products and to participate in all Government and private Tenders and Enquiries on our behalf for the full range of Surgical Instruments and Medical Equipment manufactured and offered by us.  
This agreement is valid for an indefinite period.

**PRO-MED** Instrumente GmbH

**PRO-MED**  
INSTRUMENTE GMBH  
Gänsäcker 9  
D-78532 TUTTLINGEN  
Telefon +49 71462-2042 40

**Ralph Dinkelmann**

International Sales Director, MD



Kopija tikra

Vadybini  
Daeta Rakle

Gänsäcker 9  
D-78532 Tuttlingen  
Telefon +49 (0)7462 20424-0  
FAX +49 (0)7462 20424-90  
info@pro-med-tut.de  
www.pro-med-tut.de

Sitz der Gesellschaft Tuttlingen  
Handelsregister Stuttgart HRB 460249  
Geschäftsführer Ralph Dinkelmann,  
Jan Dinkelmann  
UST-Ident.Nr. DE 142927589  
Es gelten unsere AGB

Deutsche Bank Tuttlingen Nr. 214968000  
BLZ: 65370075 BIC: DEUTDE33  
IBAN-Nr. DE22 653 700 750 2149680 00  
Commerzbank Tuttlingen Nr. 0275721700  
BLZ: 64380011 BIC: DRESDEFF643  
IBAN-Nr. DE90 643 800 110 2757217 00



QM-SYSTEM  
DIN EN ISO  
13485

**PRO-MED**

**INSTRUMENTE GMBH**

Chirurginiai instrumentai

Medicininė įranga

Pateikimui kompetentingoms  
institucijoms Lietuvoje

**Tuttlingen, 22/08/2013**

**Gamintojo įgaliojimas**

Tvirtiname, kad:

UAB OSTECA

Alytaus g. 18

LT-92307 Klaipėda

Lietuva



Kopija tikra

*vadybininkė*  
*Ūdeta Ra*

*B*

Yra įgaliotas ir oficialus platintojas M/S PRO-MED instrumentų GmbH, Tuttlingen, Lietuvoje.

UAB OSTECA yra pilnai leidžiama importuoti, platinti, pateikti rinkai, parduoti, reklamuoti ir aptarnauti mūsų produktus ir dalyvauti visuose vyriausybinuose ir privačiuose pirkimuose, parduodant mūsų vardu chirurginius instrumentus ir medicininę įrangą mūsų pagamintą ir pasiūlytą.

Ši sutartis galioja neribotą laiką.

# PRO-MED INSTRUMENTE GMBH

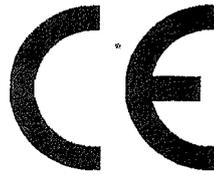
PRO-MED GmbH · Gänsäcker 9 · D-78532 Tuttlingen

CHIRURGISCHE INSTRUMENTE  
MEDIZINISCHE GERÄTE

SURGICAL INSTRUMENTS  
MEDICAL EQUIPMENT

INSTRUMENTS CHIRURGICAUX  
MATERIEL MEDICO-CHIRURGICAL

Tuttlingen, 26.01.2011



**Konformitätserklärung  
Declaration of Conformity  
Déclaration de conformité européenne  
Declaración de conformidad**

Wir / We / Nous / Nosotros:

**PRO-MED** Instrumente GmbH, Gänsäcker 9,  
78532 Tuttlingen

erklären in alleiniger Verantwortung, daß die Produkte:  
declare under our sole responsibility that the product:  
déclarons sous notre seule responsabilité, que les produit :  
declara bajo responsabilidad propia, que los productos:

**Chirurgische Instrumente  
Surgical Instruments  
Instruments de Chirurgie réutilisables  
Instrumentos quirúrgicos**

auf welche sich diese Erklärung bezieht, folgenden einschlägigen Richtlinien der EG entsprechen:  
to which this declaration relates, are in conformity with the following relevant regulations:  
auquels se réfère cette déclaration sont conformes aux normes suivantes:  
a los que se refieren esta declaración, son conformes a las siguientes normas o directrices:

**Medizinprodukterichtlinie 93/42 EWG  
Medical Device Directive 93/42 EC  
Directive pour dispositifs médicaux 93/42 CEE  
Directiva relativa a los productos sanitarios 93/42 CEE**

**PRO-MED** Instrumente GmbH

Gänsäcker 9  
D-78532 Tuttlingen  
Telefon ++49 (0) 7462/204-24-0  
Fax ++49 (0) 7462/204-24-99  
email: pro-med-tut@t-online.de  
Internet: www.pro-med-tut.de

Sitz der Gesellschaft Tuttlingen  
Handelsregister Stuttgart HRB 450249  
Geschäftsführer Roman Dinkelmann  
USt-Ident Nr. DE142927589  
FDA Reg. No. 8010733  
Es gelten unsere AGB

Deutsch Bank Tuttlingen Nr. 2 149 080  
(BLZ 653/0075) DEUT DE 55 603  
IBAN-Nr. DE22 6537 0075 0214 9680 00  
Dresdner Bank Tuttlingen Nr. 2 757 217  
(BLZ 64300011) DRES DE FF 643  
IBAN-Nr. DE90 6438 0011 0275 7217 00



PRO-MED GmbH Gansacker 9 D-78532 Tuttlingen

PRO-MED  
INSTRUMENTE GMBH  
Chirurgische Instrumente  
Medizinische Gerate

Surgical instruments  
Medical Equipment

Chirurginiai instrumentai  
Medicininė įranga

Tuttlingen, 2011 01 26

CE

Atitikties deklaracija

Mes:

M/S PRO-MED Instrumente GmbH,  
78532 Tutlingen

prisiimame visišką atsakomybę, kad produktai:

**chirurginiai instrumentai**

atitinka šias normas:

Medicinos Produktų Direktyva 93/42 CEE

PRO-MED Instrumente GmbH

Jan Dinkelmann  
Generalinis direktorius

/parašas/

Vertimas tikras: vertė Elena Solveiga Rimeikienė, UAB "Fokaja", Liepų g. 10, LT-92114 Kaipėda, Lietuva.  
Vertėjo atsakomybė pagal LR BK 235str. man žinoma.



# PRO-MED

INSTRUMENTE GMBH

Gänsäcker 9  
D-78532 Tuttlingen  
Phone: ++49 (0) 7462/204240  
FAX: ++49 (0) 7462/2042490  
eMail: PRO-MED-TUT@T-online.de  
URL: <http://www.pro-med-tut.de>

## The PRO-MED Warranty

PRO-MED warrants that all PRO-MED Instruments, marked with the PRO-MED name, shall be free from manufacturing defects in material or workmanship for the life of the instruments.

PRO-MED's sole responsibility under the warranty shall be, at PRO-MED's option, to repair or replace any instrument proving defective.

If it is determined by PRO-MED, within its absolute discretion, that an instrument is in need of repair sooner than normal use would indicate, the repair will be provided at no charge for the products indicated:

For a period of five (5) years from date code:  
Scissors, Needleholders, and Ring handle instruments  
For a period of ten (10) years from date code:  
All other date-coded instruments.

This warranty does not cover „Econoline“ Instruments, delicate instruments, bougies, malleable instruments, lenses, sterile products.

The above warranty is contingent upon the proper maintenance and use of the instruments and does not cover instruments that have been modified without PRO-MED's approval or by persons not authorized by PRO-MED, or instruments which have been subjected to unusual stress, or on which the original identification marks have been removed or altered.

Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The buyer and/or user assumes full responsibility for determining the suitability of the application of all products listed in our catalogs, offers, and other documentation and for all risks and liability associated with their use.

PRO-MED GmbH



Rainer Dinkelmann  
(Managing Director)  
Tuttlingen, 27-Aug-09



Kopija tikra

2015-04-09

Vyr. vadybinis  
Odeto Raklevič

Gansacker 9  
D-78532 Tuttlingen  
Phone: ++49(0)7462/204240  
FAX: ++49(0)7462/2042490  
eMail:PRO-MED-TUT@T-online.de  
URL:http://www.pro-med-tut.de

## PRO-MED Garantijos

PRO-MED suteikia garantiją visiems PRO-MED instrumentams, pažymėtiems PRO-MED ženklu, medžiagoms ir instrumentams neturinčioms gamybos defektų visam veikimo periodui.

PRO-MED atsako pagal garantiją pakeisti arba pataisyti instrumentus įrodančius savo trūkumus.

Jei trūkumai yra nustatomi per PRO-MED testo apžiūrą, kad priemonės yra būtina remontuoti ankščiau nei įprastai naudojama, produktams remontas bus teikiamas nemokamai:

- Penkių (5) metų laikotarpyje nuo įsigyjimo datos: žirklems, adatų laikikliams ir rankiniams instrumentams.
- Dešimties (10) metų laikotarpyje nuo įsigyjimo datos: visiems kodotiems instrumentams.

Ši garantija netaikoma "Econoline" instrumentams, subtilioms priemonėms, plėtikliams, lanksčioms priemonėms, objektyvams, steriliems produktams.

Aukščiau išvardintoms priemonėms garantija priklauso nuo tinkamos priemonės priežiūros ir naudojimo, neapima tų priemonių, kurios buvo pakeistos be PRO-MED patvirtinimo asmenims, kurie nėra leidžiami PRO-MED sąskaitos faktūros deklaracijoje, arba priemonės, kurioms buvo atliekamas neįprastas naudojimas, arba dėl kurių pirminio identifikavimo ženklo, buvo panaikintos arba pakeistos.

Tinkamas chirurgines procedūras ir metodus būtina atlikti medicinos profesijos atstovui. Pirkėjas ir / arba vartotojas prisiima visą atsakomybę, kad būtų galima nustatyti visų išvardytų produktų mūsų kataloguose, taikymo tinkamumo, bei kitus dokumentus ir visą riziką ir atsakomybę, susijusias su jų naudojimu.

PRO-MED GmbH  
Rainer Dinkelmann  
(Managing Director)  
Tuttlingen, 27-Rugpjūčio-09



Kopija tikra

2015-04-09

Vyr. vadovinė /  
Odeta Rai

Kopija tikra

Uždavinys patvirtinti

№

2016-05-19



# PRO-MED INSTRUMENTE GMBH

CHIRURGISCHE INSTRUMENTE  
MEDIZINISCHE GERÄTE

SURGICAL INSTRUMENTS  
MEDICAL EQUIPMENT

INSTRUMENTS CHIRURGICAUX  
MATÉRIEL MÉDICO-CHIRURGICAL

PRO-MED GmbH · Gänsäcker 9 · D-78532 Tuttlingen

To whom it may concern

Tuttlingen, 16.03.2015

We herewith confirm that the surgical instruments (including ENT instruments) offered by **PRO-MED** are reusable and can be washed in automatic washing / disinfecting machines and can be autoclaved/steam sterilised.

**PRO-MED** Instrumente GmbH

**PRO-MED**  
INSTRUMENTE GMBH  
Gänsäcker 9  
78532 TUTTLINGEN

PRO-MED GmbH  
Gänsäcker 9  
78532 Tuttlingen  
Tel: +49 (0)7462 20424 0  
Fax: +49 (0)7462 20424 99  
E-Mail: [info@pro-med.de](mailto:info@pro-med.de)  
[www.pro-med.de](http://www.pro-med.de)

PRO-MED Instrumente GmbH  
Handelsregister: Stuttgart HRB 450249  
Geschäftsführer: Ralf Dinkelmann  
Juro Dinkelmann  
USt-Id.Nr.: DE 142927569  
E-Mail: [info@pro-med.de](mailto:info@pro-med.de)

Deutsche Bank Tuttlingen Nr. 214068000  
BLZ 65370075 BIC: DEUTDE33HAN  
IBAN-Nr. DE22 653 700 750 2140680 00  
Commerzbank Tuttlingen Nr. 0275721700  
BLZ 64380011 BIC: COMDE33HAN  
IBAN-Nr. DE99 643 800 110 2757217 00





Vertimas iš anglų kalbos  
PRO-MED  
Chirurginiai instrumentai

OSTECA, UAB  
Alytaus g. 18,  
Klaipėda  
LIETUVA

Tutlingenas, 16/03/2016

#### KOMPETENTINGOMS INSTITUCIJOMS

Šiuo būdu patvirtiname, kad PRO-MED siūlomi chirurginiai instrumentai (įskaitant LOR instrumentus) yra daugkartinio naudojimo ir gali būti plaunami automatinėse plovimo/dezinfekavimo mašinose ir gali būti autoklavuojami/ sterilizuojami garais.

PRO-MED Instrumente GmbH

Ralph Dinkelmann  
(Parašas, antspaudas)  
Generalinis direktorius

# INTERNATIONAL STANDARD

# ISO 7153-1

Second edition  
1991-04-01

**AMENDMENT 1**  
1999-03-01

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## Surgical instruments — Metallic materials —

### Part 1: Stainless steel AMENDMENT 1

*Instruments chirurgicaux — Matériaux métalliques —*

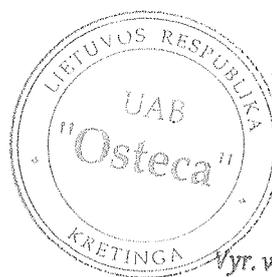
*Partie 1: Acier inoxydable*

*AMENDEMENT 1*

used for  
Surgical Instruments  
supplied by

**PRO-MED**  
INSTRUMENTE GMBH

Gänsäcker 9  
78532 Tuttlingen/Germany  
Phn + 49 7462 204240  
FAX + 49 7462 2042490  
info@pro-med-tut.de



Kopija tikra

2015-10-19

Vyr. vadybininkė  
Odetė I

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# A

Reference number  
ISO 7153-1:1991/Amd.1:1999(E)

# Surgical instruments — Metallic materials —

## Part 1: Stainless steel

### AMENDMENT 1

Page 3, table 1

At the end of table 1, add the following new row for steel grade S.

Reference letter of steel grade (see table 2)	Preferably used for		
	cutting instruments	non-cutting instruments	fitting parts and other assemblies
	Examples	Examples	Examples
<b>S</b>	scalars, chisels, dental curettes	filling instruments, dental explorers	

Page 4, table 2

In table 2 under Martensitic steels, add the following new row for steel grade S.

Steel grade			Chemical compositions, %								
Reference letter <sup>1)</sup>	Grade No. according to <sup>2)</sup>		C	Si	Mn	P	S	Cr	Mo	Ni	Other elements
	ISO 4957	ISO 683-13									
<b>Martensitic steels</b>											
<b>S</b>	—	—	0,60 to 0,75	1	1	0,04	0,03 max.	16 to 18	0,75	—	—



Kopija tikra

2015-10-19

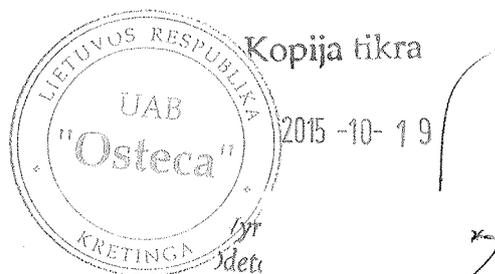
Vyr. 1  
Odeta.

## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Amendment 1 to International Standard ISO 7153-1:1991 was prepared by Technical Committee ISO/TC 170, *Surgical instruments*.



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International Organization for Standardization  
Case postale 56 CH-1211 Genève 20 Switzerland  
Internet iso@iso.ch

Printed in Switzerland

# INTERNATIONAL STANDARD

**ISO**  
**7153-1**

Second edition  
1991-04-01

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## Surgical instruments — Metallic materials —

### Part 1: Stainless steel

*Instruments chirurgicaux — Matériaux métalliques —  
Partie 1: Acier inoxydable*

used for  
Surgical Instruments  
supplied by

**PRO-MED**  
INSTRUMENTE GMBH

Gänsäcker 9  
78532 Tuttlingen/Germany  
Phn + 49 7462 204240  
FAX + 49 7462 2042490  
info@pro-med-tut.de



Reference number  
ISO 7153-1:1991(E)

# Surgical instruments — Metallic materials —

## Part 1: Stainless steel

### 1 Scope

This part of ISO 7153 contains a survey and a selection of stainless steels available for use in the manufacture of surgical, dental and specific instruments for orthopaedic surgery.

NOTE 1 When selecting the grade of steel and the shape, dimensions and delivery conditions of the raw material for manufacturing surgical instruments, it is necessary to take into account factors, such as the design of the instrument or the production facilities of the manufacturer, that are not covered by this part of ISO 7153. For this reason, it is not intended, nor is it possible, that the information given in this part of ISO 7153 should remove the decision-making responsibility from the instrument manufacturer for selecting an appropriate raw product with suitable properties; nor is it intended to preclude the use of other types of steel in the manufacture of instruments, such as the use of carbon steel for cutting instruments. International Standards for surgical instruments, when published, should be observed when making this decision as they may contain additional or new infor-

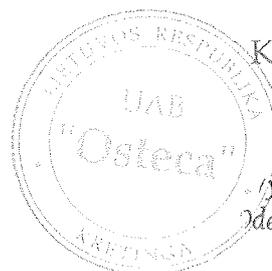
mation to be taken into account when selecting appropriate steel grades.

### 2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7153. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7153 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 683-13:1986, *Heat-treatable steels, alloy steels and free-cutting steels — Part 13: Wrought stainless steels.*

ISO 4957:1980, *Tool steels.*



3 Survey

Table 1 — Steel grades

Reference letter of steel grade (see table 2)	Preferably used for		
	cutting instruments	non-cutting instruments	fitting parts and other assemblies
	Examples	Examples	Examples
A		tissue forceps, dressing forceps, retractors, probes, dental tweezers	rivets, solid handles, guide pins, screws, nuts
B	bone rongeurs, bone-cutting forceps, conchotomes, chisels and gouges, bone curettes, scissors with carbide inserts	forceps, forceps with bow handles, branch forceps, retractors, probes, dental extraction forceps, laboratory and orthodontic pliers, dental explorers, root elevators, filling instruments, dental tweezers	springs, solid handles, screws, nuts, rivets
C	bone rongeurs, scissors, scalers, dental curettes, dental chisels	laboratory and orthodontic pliers, dental explorers, dental tweezers, dental extraction forceps, root elevators, filling instruments	
D	scissors, bone rongeurs, bone-cutting forceps, conchotomes, scalpels, knives, chisels and gouges, bone curettes, wire-cutting pliers, scalers, dental curettes, dental chisels, drills, taps, countersink cutters	root elevators, dental explorers, filling instruments	
E	scalpels		
F	scalpels		
G	scalpels, chisels and gouges, shears		



Kopija tikra

2015-11-16

yr. vady  
Odetta Raki

3

Reference letter of steel grade (see table 2)	cutting instruments	Preferably used for non-cutting instruments	fitting parts and other assemblies
	Examples	Examples	Examples
H	scissors, bone rongeurs, conchotomes, chisels and gouges, bone curettes, wire-cutting pliers, drills, taps, countersink cutters		
I	scissors, bone rongeurs, bone-cutting forceps, conchotomes, scalpels, knives, chisels and gouges, bone curettes, wire-cutting pliers drills, taps, countersink cutters		
K	chisels and gouges, bone curettes		
L			solid handles, guide pins, screws, nuts
M		retractors, impression trays	hollow handles, guide pins, rivets, screws
N	chisels and gouges, bone curettes	probes	solid handles, guide pins, screws, nuts, rivets
O		dental explorers	springs, screws, rivets
P			screws, rivets
R	scalers, chisels, dental curettes, drills, taps, countersink cutters	filling instruments, dental explorers, laboratory and orthodontic pliers	



Kopija tikra

2015-11-16

"Ostecca" / yr. vadovtinkė  
Odeta

**4 Chemical composition**

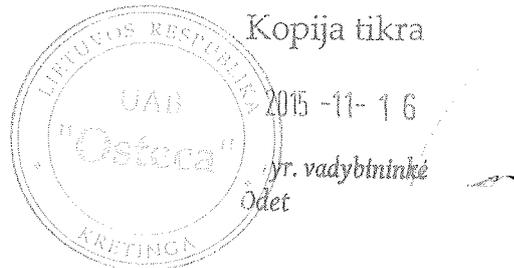
The chemical composition of those steels specified in ISO 4957 and ISO 683-13, indicated by grade numbers, are given for information only.

The chemical composition of the steels shall be in accordance with table 2.

**Table 2 — Steel grades and specified chemical compositions (cast analysis)**

Elements not quoted in table 2 shall not be intentionally added to the steel without the agreement of the purchaser, other than for the purpose of finishing the heat. All reasonable precautions shall be taken to prevent the addition, from scrap or other material used in manufacture, of such elements which affect hardenability, mechanical properties and applicability.

Reference letter <sup>1)</sup>	Steel grade Grade No. according to <sup>2)</sup>		C	Si max.	Mn max.	P max.	Chemical compositions, %					Other elements
	ISO 4957	ISO 683-13					S	Cr	Mo	Ni		
<b>Martensitic steels</b>												
A	—	3	0,09 to 0,15	1	1	0,04	0,03 max.	11,5 to 13,5	—	1 max.		
B	27	4	0,16 to 0,25	1	1	0,04	0,03 max.	12 to 14	—	1 max.		
C	28	5	0,26 to 0,35	1	1	0,04	0,03 max.	12 to 14	—	1 max.		
D	—	—	0,42 to 0,50	1	1	0,04	0,03 max.	12,5 to 14,5	—	1 max.		
E	—	—	0,47 to 0,57	0,5	1	0,03	0,025 max.	13,7 to 15,2	—	0,5 max.		
F	—	—	0,6 to 0,7	0,5	1	0,03	0,025 max.	12 to 13,5	—	0,5 max.		
G	—	—	0,65 to 0,75	1	1	0,04	0,03 max.	12 to 14	0,5 max.	1 max.		
H	—	—	0,35 to 0,4	1	1	0,045	0,03 max.	14 to 15	0,4 to 0,6	—	V: 0,1 to 0,15	
I	—	—	0,42 to 0,55	1	1	0,045	0,03 max.	12 to 15	0,45 to 0,9	—	V: 0,1 to 0,15	
K	30	—	0,33 to 0,43	1	1	0,03	0,03 max.	15 to 17	1 to 1,5	1 max.		
R	—	—	0,85 to 0,95	1	1	0,045	0,03 max.	17 to 19	0,9 to 1,3	—	V: 0,07 to 0,12	
<b>Ferritic steels</b>												
L	—	8a	0,08 max.	1	1,5	0,06	0,15 to 0,35	16 to 18	0,6 max.	1 max.		
<b>Austenitic steels</b>												
M	—	11	0,07 max.	1	2	0,045	0,03 max.	17 to 19	—	8 to 11		
N	—	17	0,12 max.	1	2	0,06	0,15 to 0,35	17 to 19	--3)	8 to 10		
O	—	14	0,15 max.	1	2	0,045	0,03 max.	16 to 18	—	6 to 8		
P	—	20	0,07 max.	1	2	0,045	0,03 max.	16,5 to 18,5	2 to 2,5	10,5 to 13,5		
<p>1) The reference letters are used for the purpose of cross-referencing.</p> <p>2) The grade numbers are provisional and will be subject to alteration when the relevant International Standards are published.</p> <p>3) The manufacturer has the option of adding molybdenum up to 0,7 %.</p>												



## Foreword

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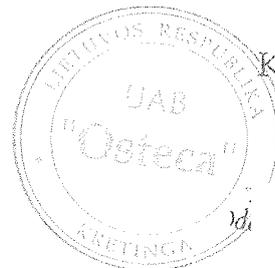
International Standard ISO 7153-1 was prepared by Technical Committee ISO/TC 170, *Surgical instruments*.

This second edition cancels and replaces the first edition (ISO 7153-1:1983); it has been extended to include dental instruments.

ISO 7153 consists of the following parts, under the general title *Surgical instruments — Metallic materials*:

- Part 1: *Stainless steel*

Future parts of ISO 7153 will cover other metallic materials.



Kopija tikra

2015-11-16

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Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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FAX: +49 (0) 7462 / 2042490

e-mail: pro-med-tut@t-online.de

Internet: www.pro-med-tut.de

Osteca, UAB

Alytaus str. 18,

Klaipeda

LITHUANIA

Tuttlingen, 29/06/2011

FOR PRESENTATION TO THE COMPETENT AUTHORITIES IN LITHUANIA

## CERTIFICATE OF STANDARDS

We, PRO-MED Instrumente GmbH, herewith certify that our products are all manufactured from stainless steel according to an international DIN EN ISO 7153-1 standard.



Ralph Dinkelmann  
International Sales Manager  
Managing Director



Kopija tikra

2015-11-16

UAB "Osteca"  
R. Dinkelmann  
Managing Director

Vertimas iš anglų kalbos

PRO-MED

Chirurginių instrumentų gamyba

Osteca, UAB

Alytaus g. 18,

Klaipėda

LIETUVA

Tutlingenas, 29/06/2011

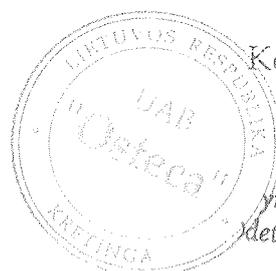
KOMPETETINGOMS INSTITUCIJOMS LIETUVOJE

### PAŽYMA APIE STANDARTUS

Mes, PRO-MED Instrumente GmbH, šiuo pažymime, kad visa mūsų produkcija yra gaminama iš nerūdijančio plieno, atsižvelgiant į tarptautinį DIN EN ISO 7153-1 standartą.

Ralph Dinkelmann

Tarptautinių pardavimų vadovas, MD



Kopija tikra

2015-11-16

yr. vadybtinkė  
Jolita Raklevičienė



Foreseeson GmbH  
Industriestr. 38a  
D-63150 Heusenstamm  
Tel: 06104/64398-0  
Fax: 06104/64398-11

Foreseeson GmbH, Industriestr. 38a, D-63150 Heusenstamm

To whom it may concern.

25.04.2022

Letter of Authorization

FORESEESON GmbH declare that:

**OSTECA, UAB**  
Danes str. 47,  
Klaipeda  
Lithuania

is authorized and has the right to re-sell the FSN production in the Lithuanian market.  
This letter is valid until 31.12.2022.

Business Development Manager:

A handwritten signature in black ink, appearing to read "Anna Kisqk-Swatkowska".

*Anna Kisqk-Swatkowska*

**FORESEESON GmbH**  
Industriestr. 38a  
Heusenstamm, Germany  
tel.: +49 6104 643 980

Foreseeson GmbH  
Industriestr. 38a  
D-63150 Heusenstamm  
Tel; 06104/64398-0  
Fax: 06104/64398-11

Foreseeson GmbH, Industriestr. 38a, D-63150 Heusenstamm

Tam, kuriam tai gali būti aktualu,

2022.04.25

### Įgaliojimo laiškas

FORESEESON GmbH skelbia, kad:

OSTECA, UAB  
Danės g. 47  
Klaipėda  
Lietuva

Yra įgaliota platinti FSN produkciją Lietuvos rinkoje.  
Šis laiškas galioja iki 31.12.2022

/parašas/

Verslo vystymo vadovas:  
Anna Kisalk Swatkowska



## EC DECLARATION OF CONFORMITY

**Manufacturer:** Foreseeson Custom Displays, Inc.  
2210 E. Winston Road  
Anaheim, CA 92806 USA

**Authorized Representative:** Foreseeson GmbH  
Industriestrasse 38a  
63150 Heusenstamm, Germany

**Model Number:** FM-A2701D / FM-A2701DS

**Product Name:** LCD Color Display

**Product Description:** LCD Color Display

**Device Risk Class:** Class 1 per Rules 1 and 12 of Annex IX,  
Council Directive 93/42/EEC

We, Foreseeson Custom Displays Inc., declare that the above named product(s) conform to the essential requirements of the following European Union Directive(s):

- **Medical Device Directive 93/42/EEC**
- **2011/65/EU European RoHS 2 Directive**

The following harmonized standards and specifications have been used and are listed by specific reference to the essential requirements of the referenced Directives:

### **Medical Device Directive 93/42/EEC**

EN 60601-1-2:2015, EN 55011:2009 +A1:2010 (Group 1 Class B), EN 61000-3-2:2014, EN 61000-3-3:2013,  
EN 61000-4-2:2009, EN 61000-4-3:2006 +A1:2008+A2:2010, EN 61000-4-4:2012, EN 61000-4-5:2014,  
EN 61000-4-6:2014, EN 61000-4-11:2004

### **IECEE CB Scheme**

IEC 60601-1(ed.3), IEC 60601-1(ed.3); am1, IEC 60601-1-6(ed.3), IEC 60601-1-6(ed.3); am1

### **2011/65EU European RoHS 2 Directive**

EN50581:2012

The Technical Construction File (TCF), relevant to the product(s) described above and which support this DoC, is available from the Authorized Representative at the address stated above.

*Signed on behalf of Foreseeson Custom Displays Inc.*

A handwritten signature in black ink, appearing to read "Robert Contreras".

**Robert Contreras**

QA Manager

FORESEESON Custom Displays, Inc.

2210 E. WINSTON Rd.  
ANAHEIM, CA 92806

Place of Issue: Foreseeson Custom Displays Inc., 2210 E. Winston Road, Anaheim, CA 91770 USA

Date of Issue: July 31, 2018

## CE ATITIKTIES DEKLARACIJA

Gamintojas: Foreseeson Custom Displays, Inc.  
2210 E. Winston Road  
Anaheim, CA 92806 JAV

Igaliotas platintojas: Foreseeson GmbH  
Industriestr. 38a  
D-63150 Heusenstamm, Vokietija

Modelio numeris: FM-A2701D / FM-A2701DS

Produkto pavadinimas: LCD spalvotas monitorius

Produkto aprašymas: LCD spalvotas monitorius

Prietaiso rizikos klasė: 1klasė, Priedo IX taisyklės 1 ir 12  
Tarybos direktyva 93/42/EEC

Mes, Foreseeson Custom Displays Inc. Patvirtiname, kad aukščiau nurodytas produktas atitinka esminius toliau sekančios Europos sąjungos direktyvos reikalavimus:

- Medicininių prietaisų direktyva 93/42/EEC
- 2011/65/EU Europos RoHS 2 direktyvą

Šie suderinti standartai ir specifikacijos turi būti naudojami ir yra išvardyti pagal specifinius kodus, atitinkančius esminius nurodytos Direktyvos reikalavimus:

Medicininių prietaisų direktyva 93/42/CE

EN 60601-1-2:2015, EN 55011:2009 + A1:2010 (1grupė, B klasė), EN 61000-3-2:2014, EN 61000-3-3:2013, EN 61000-4-2:2009, EN 61000-4-3:2006 +A1:2008+A2:2010, EN 61000-4-4:2012, EN 61000-4-5:2014, EN 61000-4-6:2014, EN 61000-4-11:2004

IECEE CB schema

IEC 60601-1 (ed.3), IEC 60601-1 (ed.3); am1, IEC 60601-1-6 (ed.3), IEC 60601-1-6 (ed.3); am1

2011/65UE Europos RoHs 2 Direktyva  
EN50581:2012

Techninės konstrukcijos failas (TCF), aktualus produktams, nurodytiems aukščiau ir kurie palaiko DoC, yra prieinamas per Igaliotą platintoją aukščiau nurodytu adresu.

Pasirašyta Foreseeson Custom Displays Inc. vardu  
/parašas/  
Robert Contreras  
QA vadovas

Išleidimo vieta: Foreseeson Custom Displays Inc. 2210 E. Winston Road, Anaheim, CA 91770 JAV

Išleidimo data: 2018 m. liepos 31 d.

**Atitikimo pažymėjimas**  
Remiantis  
**EMC Collateral standartu**  
**Medicinos įrenginių direktyva 93/42/EEC**

Pažymėjimo nr.	EMC16141-12-04
Produktas	Medical LCD Monitor
Modelis / Keitimo identifikavimo kodas	FS-P2601D, FS-P260*D
Pažymėjimo išdavėjas	D&T Inc.Daedeok slėnis, 59-9, Jang dong, Yuseong gu, Daejeon, Korėja, 305-343
Gamintojas:	Tas pats, kaip ir pažymėjimo išdavėjas
Prekės ženklas	Nenurodyta
Elektrinis įvertinimas	100-240Vac, 50/60Hz, 2,5A
Papildoma informacija	Gamintojas priskiria visus produktų modelius prie įprasto modelio, be jokių papildomų vertinimų atliktų UL.

Šis pažymėjimas galioja tik produktams priduotiems Underwriters Laboratories patvirtinimui, kurie yra identiški išbandytiems ir patvirtintiems produktams. Pavyzdžiu yra patvirtinta, kad produktas buvo patikrintas ir atitinka žemiau pateiktus standartus:

Standartas: EN 60601-1-2: 2007 (IEC 60601-1-2:2007)

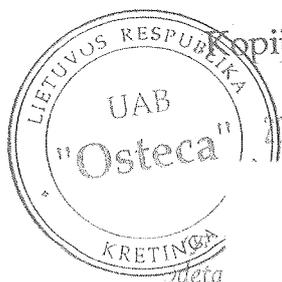
Detalesnė specifikacija testuotų ir pažymėtų produktų yra nurodyti žemiau esančiame testavimo pranešime (Test Report):

Testavimo pranešimo nr. 12CA39455-CE Išleidimo data: 2012-10-15 Leidėjas: UL Korea Ltd.

Šalys narės Europoje numato laikytis nuostatų, susijusių su saugumo reikalavimais, nurodytais EMC standard of Medical Device Directive 93/42/EEC, sudarytą 1993 birželio 14, kai produktas turi CE – ženklo atitikimą. Atitikimo pažymėjimas su medicinos įrangos direktyva yra pabaigta ir pasirašyta gamintojo arba įgalioto atstovo. Panašūs dokumentai galimi kreipiantis į gamintoją arba įgaliotąjį. Šis dokumentas yra 1 lapo.

Data: 2012-10-19

Parašas  
YongJin, Suk  
Sertifikato vadybininkas  
Atitikites įvertinimo paslaugos



UL Korea Ltd.  
33 aukštas Gangnam finaucų centras 737,  
Yeoksam-dong, Gangnam-gu, Seoul, Korėja  
efonas: +82 2 2009 9000 Faksas: +82 2 2009 9404

**CERTIFICATE OF CONFORMITY**

According to  
**EMC Collateral Standard**  
**Medical Device Directive 93/42/EEC**

Certificate No.	EMC16141-12-04
Product	Medical LCD Monitor
Model /Trade ref.	FS-P2601D, FS-P260*D
Holder of Certificate	D&T INC. DAEDEOK VALLEY, 59-9, JANG DONG, YUSEONG GU, DAEJEON, KOREA, 305-343
Manufacturer	Same as applicant
Trade Mark	N/A
Electrical Rating	100-240Vac, 50/60Hz, 2.5A
Additional Information	The manufacturer has declared to all the multiple model names into the basic model without any further evaluation by UL.

This certificate is only valid for products submitted to Underwriters Laboratories for certification, which are identical to the tested and certified product(s). It is confirmed that a sample of the product has been tested and found in conformity with the following standard(s):

Standard(s): EN 60601-1-2: 2007 (IEC 60601-1-2:2007)

Detailed specification of the tested and certified product are shown in the following Test Report:

Test Report Ref. No.: 12CA39455-CE      Issued Date: 2012-10-15      By: UL Korea Ltd.

The Member States of the EU shall presume compliance with the provisions of general safety requirement of collateral EMC standard of the Medical Device Directive 93/42/EEC of 14 June 1993 when the product is carrying the CE-mark of conformity, a Declaration of Conformity with the Medical Device Directive has been completed and signed by the manufacturer or his authorized representative established within the Community, and the relevant documentation is available.

This document contains 1 page(s).

Date: 2012-10-19



S  
 YongJin, Suk  
 Certification Manager  
 Conformity Assessment Services



**UL Korea Ltd.**  
 33<sup>rd</sup> Fl. Gangnam Finance Center 737,  
 Yeoksam-dong, Gangnam-gu, Seoul, Korea  
 Telephone: +82 2 2009 9000 Fax: +82 2 2009 9404