World Health Organization

Anexă

Digitally signed by Ceaicovschi Tudor
Date: 2023.12.28 00:28:29 EET
Reason: MoldSign Signature
Location: Moldova

Anexa 11

Achiziție container de sterilizare medical (47x30x16)

Lista cerințelor și specificațiilor

Recipient de sterilizare medicală					
NUME, CATEGORIA ȘI CODIFICARE					
	Parametrii		**Specificație minimă așteptată**	**Caietul de sarcini propus (de completat de ofertant)**	**Documentul de referință / broșura / pagina în care informațiile furnizate pot fi verificate de către comisia de evaluare**
1	Nume generic	Containerele de sterilizare sunt proiectate pentru un flux perfect de abur și o penetrare a încărcăturilor, potrivite standardelor și pot fi utilizate cu filtru de hârtie de unică folosință sau filtre reutilizabile. CAPACELE DE SIGURANȚĂ trebuie să fie în set pentru păstrarea unui material sterilizat.		**MODEL: 260-205-18Y Producător: TONTARRA Țara: Germania**	
CARACTERISTICI TEHNICE și CARACTERISTICI FIZICE					
2	CADRU, CORP	Carcasă dreptunghiulară	da	DA	Din broshura atasta
3	DATE	Dimensiune 47x30x16 cm, ±2 cm	da	DA 47x27x18 cm	Din broshura atasta
		Tăvi din plasă în interior	2	DA	Din broshura atasta
		CAPACE DE SIGURANȚĂ	da	DA	Din broshura atasta
		materialul corpului	aliaj de aluminiu cu finisaj anodizat/oțel inoxidabil	DA aliaj aluminium cu finisaj anodizat	Din broshura atasta TONTARRA
		Minere pentru transportare	da	DA	Din broshura atasta TONTARRA
		potrivit pentru sterilizare gravitațională	da	DA	Din broshura atasta TONTARRA
		tip de filtre	Filtru reutilizabil PTFE teflon/ FILTRU DE HÂRTIE/ FILTRU TEXTIL	DA este compatibil cu ficare din filtru indicata	Din broshura atasta TONTARRA

		plăci de filtrare cu mecanism simplu de blocare pentru schimbarea rapidă, sigură și ușoară a filtrelor de unică folosință	da	DA	
ACCESORII, CONSUMABILE, PIESE DE SCHIMB, ALTE COMPONENTE					
4	Accesorii/ piese de schimb	tavă pentru instrument de Chirurgie generală	2	DA	PN 260-290-10Y
		set de filtre (1000 bucăți hârtie, sau 10 din PTFE teflon sau 100 din material textil)	1	DA	PN 260-800-00Y
INSTRUIRE, INSTALARE SI UTILIZARE					
5	Transport	Furnizorul trebuie să includă transportul până la unitatea medicală finală	da	DA	
6	Instalare	Furnizorul trebuie să efectueze verificările de instalare, siguranță și funcționare înainte de predare, instruire pentru utilizatori și tehnicieni	da	DA	
GARANȚIE ȘI ÎNTREȚINERE					
7	Garanție și deservire completă (inclusiv piese de schimb)	minim 24 luni	da	DA	
DOCUMENTAȚIE					
8	Cerințe de documentare	Toate documentele justificative, manualele de operare, de service trebuie prezentate în limba de stat sau în limba engleză. Manualul de utilizare/Instructiunile de utilizare trebuie prezentate în limba engleză și în limba de stat.	da	DA	
SIGURANȚĂ ȘI STANDARDE					
9	Standarde pentru producător	1. Certificat de conofmritate CE și sau Declarația de conformitate CE 2. ISO 9001 și/sau 13485 3. EN 868 Partea 8 DIN 58953 Partea 9 4. Aprobat pentru sterilizare cu abur în conformitate cu EN 285 și validat în conformitate cu ISO 17665 Partea 1	toate certificatele trebuie prezentate în copii cu ștampila de confirmare	DA	Certificatele Atasate

World Health Organization

Anexă

Anexa 12

Achiziție container de sterilizare medical (30x30x21)

Lista cerințelor și specificațiilor

Recipient de sterilizare medicală					
NUME, CATEGORIA ȘI CODIFICARE					
	Parametrii		**Specificație minimă așteptată**	**Caietul de sarcini propus (de completat de ofertant)**	**Documentul de referință / broșura / pagina în care informațiile furnizate pot fi verificate de către comisia de evaluare**
1	Nume generic	Containerele de sterilizare sunt proiectate pentru un flux perfect de abur și o penetrare a încărcăturilor, potrivite standardelor și pot fi utilizate cu filtru de hârtie de unică folosință sau filtre reutilizabile. CAPACELE DE SIGURANȚĂ trebuie să fie în set pentru păstrarea unui material sterilizat.		**MODEL: 260-305-20Y Producător: TONTARRA Țara: Germania**	
CARACTERISTICI TEHNICE și CARACTERISTICI FIZICE					
2	CADRU, CORP	Carcasă dreptunghiulară	da	DA	
3	DATE	Dimensiune 30x30x21 cm, ±2cm	da	DA 31x27x19 cm	Din broshura atasta
		Tăvi din plasă în interior	2	DA	Din broshura atasta
		CAPACE DE SIGURANȚĂ	da	DA	Din broshura atasta
		materialul corpului	aliaj de aluminiu cu finisaj anodizat/oțel inoxidabil	DA aliaj aluminium cu finisaj anodizat	Din broshura atasta TONTARRA
		Minere pentru transportare	da	DA	Din broshura atasta TONTARRA
		potrivit pentru sterilizare gravitațională	da	DA	Din broshura atasta TONTARRA
		tip de filtre	Filtru reutilizabil PTFE teflon/ FILTRU DE HÂRTIE/ FILTRU TEXTIL	DA este compatibil cu ficare din filtru indicata	Din broshura atasta TONTARRA
		plăci de filtrare cu mecanism simplu de blocare pentru schimbarea rapidă, sigură și ușoară a filtrelor de unică folosință	da	DA	Din broshura atasta TONTARRA

ACCESORII, CONSUMABILE, PIESE DE SCHIMB, ALTE COMPONENTE					
4	Accesorii/ piese de schimb	tavă pentru instrument de Chirurgie generală	2	DA	PN 260-390-10Y
		set de filtre (1000 bucăți hârtie, sau 10 din PTFE teflon sau 100 din material textil)	1	DA	PN 260-800-00Y
INSTRUIRE, INSTALARE SI UTILIZARE					
5	Transport	Furnizorul trebuie să includă transportul până la unitatea medicală finală	da	DA	
6	Instalare	Furnizorul trebuie să efectueze verificările de instalare, siguranță și funcționare înainte de predare, instruire pentru utilizatori și tehnicieni	da	DA	
GARANȚIE ȘI ÎNTREȚINERE					
7	Garanție și deservire completă (inclusiv piese de schimb)	minim 24 luni	da	DA	
DOCUMENTAȚIE					
8	Cerințe de documentare	Toate documentele justificative, manualele de operare, de service trebuie prezentate în limba de stat sau în limba engleză. Manualul de utilizare/Instructiunile de utilizare trebuie prezentate în limba engleză și în limba de stat.	da	DA	
SIGURANȚĂ ȘI STANDARDE					
9	Standarde pentru producător	1. Certificat de conofmritate CE și sau Declarația de conformitate CE 2. ISO 9001 și/sau 13485 3. EN 868 Partea 8 DIN 58953 Partea 9 4. Aprobat pentru sterilizare cu abur în conformitate cu EN 285 și validat în conformitate cu ISO 17665 Partea 1	toate certificatele trebuie prezentate în copii cu ștampila de confirmare	DA	Certificatele Atasate

TONTARRA

OVERVIEW

CONTAINER SYSTEM FOR STERILIZATION

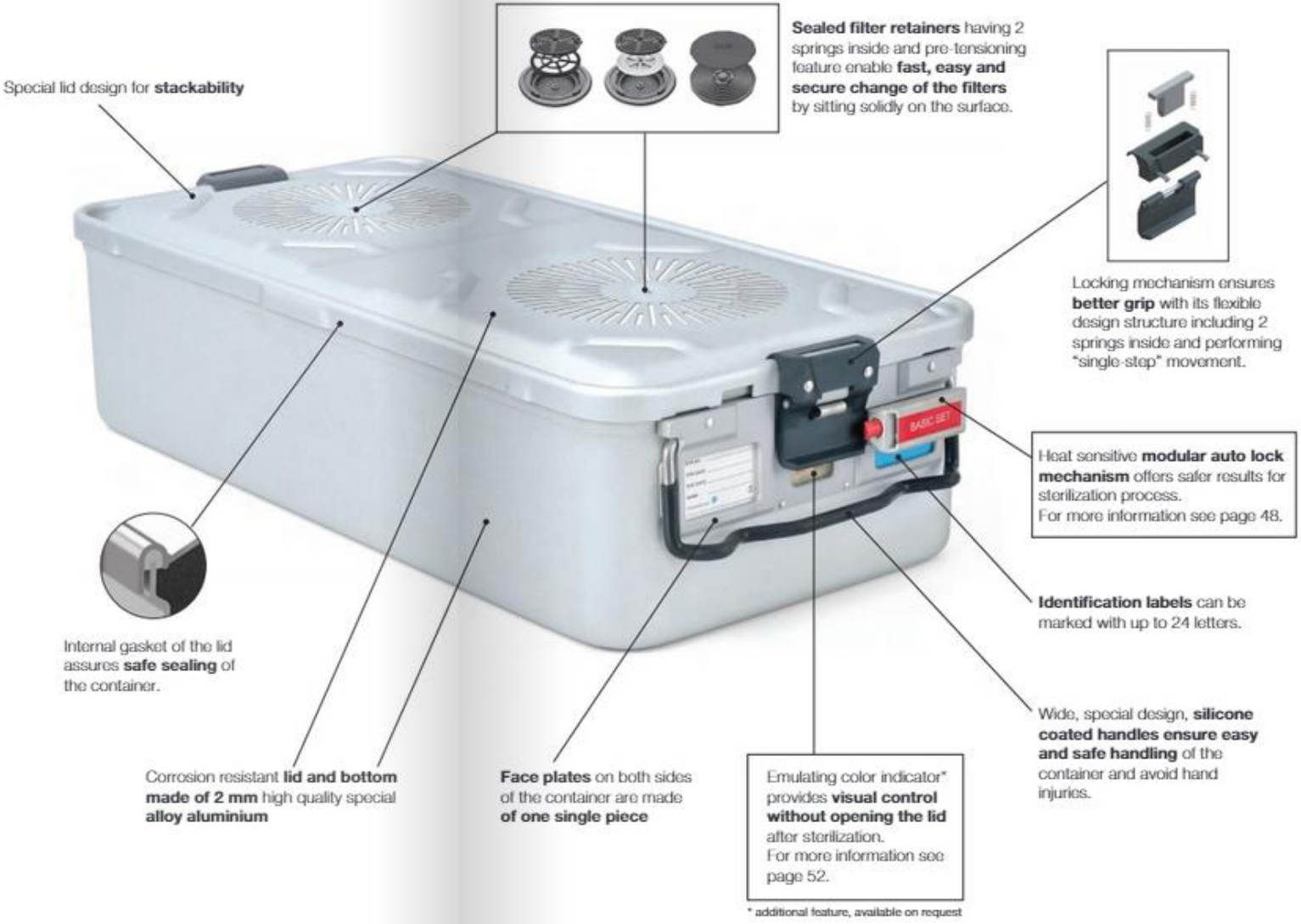

STANDARD MODEL


B3 MODEL


MINI CONTAINER


OPTIC CASES


REMOVAL CONTAINER



STANDARD MODEL

1/1 FULL SIZE

3/4 QUARTER SIZE

1/2 HALF SIZE

TONTARRA

STANDARD MODEL

- Corrosion resistant lid and bottom made of 2 mm high quality special alloy aluminium.
- Use with single-use paper filters or reusable PTFE teflon filters.
- Heat sensitive modular auto lock mechanism (optional) offers safer results for sterilization process.
- Emulating color indicator* provides visual control opening the lid after sterilization.
- Equipped with silicone coated carrying handles with 90° mobility for easy & secure carrying.
- Gasket inside the lid and filter retainer ensures secure tightness.
- Locking mechanism provides excellent grip with its flexible structure.
- Non-perforated and perforated containers.
- Perforated lids and safety lids for effective external protection.
- Safety lids for protection of the perforated lid and the filter system against hard objects, liquids and dust for specific baskets and accessories.

* additional feature, available on request

STANDARD MODEL

1/1
Full Size

ACCESSORIES

FILTER DISPENSER

260-801-00Y

AUTO LOCK MECHANISM

260-855-00Y
(2 Pcs)

SECURITY SEAL *(red)*

260-819-01Y
100 pcs.
with indicator
made of plastic

DISPOSAL STAMP

260-849-02Y
40 x 35 x 9 mm
Requested number or letter must be informed during the order.

SECURITY SEAL *(blue)*

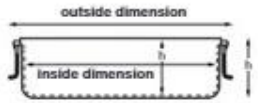
260-819-00Y
100 pcs.
made of plastic

WRAPPING DRAPES *(cotton)*

260-095-07Y
1300 x 600 mm
260-095-08Y
1400 x 1000 mm
260-095-09Y
1850 x 450 mm
260-095-10Y
1850 x 600 mm

STANDARD MODEL

3/4
Quarter Size



BOX *(non perforated)*

Art. No.	outside dimension	inside dimension	weight
260-205-10Y	475 x 272 h:100 mm	422 x 258 h:94 mm	1609 g
260-205-13Y	475 x 272 h:116 mm	422 x 258 h:110 mm	1714 g
260-205-15Y	475 x 272 h:138 mm	422 x 258 h:132 mm	1842 g
260-205-18Y	475 x 272 h:185 mm	422 x 258 h:179 mm	2117 g

BOX *(perforated)*

Art. No.	outside dimension	inside dimension	weight
260-206-10Y	475 x 272 h:100 mm	422 x 258 h:83 mm	1792 g
260-206-13Y	475 x 272 h:116 mm	422 x 258 h:99 mm	1836 g
260-206-15Y	475 x 272 h:138 mm	422 x 258 h:121 mm	1980 g
260-206-18Y	475 x 272 h:185 mm	422 x 258 h:168 mm	2240 g

PERFORATED LIDS

Art. No.	color	weight
260-200-01Y		1014 g
260-200-02Y		
260-200-05Y		
260-200-04Y		
260-200-03Y		
260-200-06Y		

Dimension: 477 x 285 mm

REMOVAL LIDS *(non perforated)*

Art. No.	color	weight
260-202-01Y		940 g
260-202-02Y		
260-202-05Y		
260-202-04Y		
260-202-03Y		
260-202-06Y		

Dimension: 477 x 285 mm

SAFETY LIDS

Art. No.	color	weight
260-203-01Y		903 g
260-203-02Y		
260-203-05Y		
260-203-04Y		
260-203-03Y		
260-203-06Y		

Dimension: 483 x 290 mm

STANDARD MODEL

3/4
Quarter Size

BASKET MADE FROM STAINLESS STEEL WIRE MESH

WIRE BASKET

Art. No.	outside dimension
260-290-03Y	405 x 245 x h:30 mm
260-290-05Y	405 x 245 x h:50 mm
260-290-07Y	405 x 245 x h:70 mm
260-290-10Y	405 x 245 x h:100 mm

ONLY LID

Art. No.	outside dimension
260-290-00Y	ONLY LID, for baskets 405 mm

WIRE BASKET WITH PERFORATED METAL PLATE

WIRE BASKET

Art. No.	outside dimension
260-290-05YPP	405 x 246 x h:50 mm
260-290-07YPP	405 x 246 x h:70 mm
260-290-10YPP	405 x 246 x h:100 mm

ONLY LID

Art. No.	outside dimension
260-290-00YPP	ONLY LID, for baskets 405 mm

TONTARRA

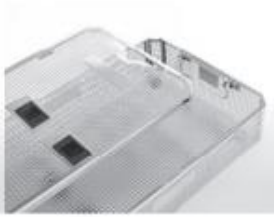
STANDARD MODEL

3/4
Quarter Size

BASKET MADE FROM STAINLESS STEEL WIRE MESH

BASKET *(with stand)*

	Art. No.	outside dimension
Box	**270-290-03Y**	405 x 253 h:40 mm
	270-290-05Y	405 x 253 h:60 mm
	270-290-07Y	405 x 253 h:80 mm
	270-290-10Y	405 x 253 h:110 mm
Lid	**270-290-00Y**	ONLY LID, for baskets



The baskets which are less than 44 mm in height do not include the handles.

STAND

Art. No.	height
260-825-20Y	20 mm

STAND

Art. No.	height
260-825-14Y	10 mm

WIRE BASE

Art. No.	dimension
260-293-03Y	405 x 255 x 30 mm

STANDARD MODEL

3/4
Quarter Size

ACCESSORIES

DRAPE RETAINER

260-295-00Y
405 x 255 mm

SILICONE MAT

260-852-10Y - green
260-852-11Y - blue
380 x 230 mm

SILICONE HANDLE

260-822-03Y
260-822-02Y
260-822-05Y
260-822-04Y
260-822-01Y
260-822-06Y

DISPOSABLE SINGLE USE PAPER FILTER

260-800-00Y
with steam indicator
500 pcs. /box

PTFE/TEFLON FILTER REUSABLE

260-800-03Y
Period of use approx. 2000 sterilization cycles
1 pc./box

LABELS *(paper)*

260-810-00Y
1000 pcs.

IDENTIFICATION LABELS *(aluminium)*

260-820-03Y
260-820-04Y
260-820-05Y
260-820-02Y
260-820-01Y
260-820-06Y

FILTER DISPENSER

260-801-00Y

AUTO LOCK MECHANISM

260-855-00Y
(2 Pcs)

TONTARRA

STANDARD MODEL

3/4
Quarter Size

ACCESSORIES

SECURITY SEAL *(red)*

260-819-01Y
100 pcs.
with indicator
made of plastic

DISPOSAL STAMP

260-849-02Y
40 x 35 x 9 mm
Requested number or letter must be informed during the order.

SECURITY SEAL *(blue)*

260-819-00Y
100 pcs.
made of plastic

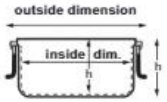
WRAPPING DRAPES *(cotton)*

260-095-08Y
1400 x 1000 mm

Assembly & disassembly method of safety lid for safe model containers.

STANDARD MODEL

1/2 Half Size



BOX *(non perforated)*

Art. No.	outside dimension	inside dimension	weight
260-305-10Y	310 x 272 h:100 mm	253 x 258 h:94 mm	1267 g
260-305-13Y	310 x 272 h:116 mm	253 x 258 h:110 mm	1315 g
260-305-15Y	310 x 272 h:138 mm	253 x 258 h:132 mm	1427 g
260-305-20Y	310 x 272 h:190 mm	253 x 258 h:184 mm	1660 g
260-305-26Y	310 x 272 h:235 mm	253 x 258 h:229 mm	1940 g

BOX *(perforated)*

Art. No.	outside dimension	inside dimension	weight
260-306-10Y	310 x 272 h:100 mm	253 x 258 h:83 mm	1385 g
260-306-13Y	310 x 272 h:116 mm	253 x 258 h:99 mm	1417 g
260-306-15Y	310 x 272 h:138 mm	253 x 258 h:121 mm	1590 g
260-306-20Y	310 x 272 h:190 mm	253 x 258 h:173 mm	1821 g
260-306-26Y	310 x 272 h:235 mm	253 x 258 h:218 mm	1947 g

PERFORATED LIDS

Art. No.	color	weight
260-300-01Y		727 g
260-300-02Y		
260-300-05Y		
260-300-04Y		
260-300-03Y		
260-300-06Y		

Dimension: 312 x 280 mm

REMOVAL LIDS *(non perforated)*

Art. No.	color	weight
260-302-01Y		629 g
260-302-02Y		
260-302-05Y		
260-302-04Y		
260-302-03Y		
260-302-06Y		

Dimension: 312 x 280 mm

SAFETY LIDS

Art. No.	color	weight
260-303-01Y		775 g
260-303-02Y		
260-303-05Y		
260-303-04Y		
260-303-03Y		
260-303-06Y		

Dimension: 317 x 285 mm

TONTARRA

STANDARD MODEL

1/2 Half Size

BASKET MADE FROM STAINLESS STEEL WIRE MESH

WIRE BASKET

Art. No	outside dimension
260-390-03Y	246 x 246 x h:30 mm
260-390-05Y	246 x 246 x h:50 mm
260-390-07Y	246 x 246 x h:70 mm
260-390-10Y	246 x 246 x h:100 mm

ONLY LID

Art. No.	outside dimension
260-390-00Y	ONLY LID, for baskets 246 mm

WIRE BASKET WITH PERFORATED METAL PLATE

WIRE BASKET

Art. No	outside dimension
260-390-05YPP	246 x 246 h:50 mm
260-390-07YPP	246 x 246 h:70 mm
260-390-10YPP	246 x 246 h:100 mm

ONLY LID

Art. No.	outside dimension
260-390-00YPP	ONLY LID, for baskets 246 mm

STANDARD MODEL

1/2 Half Size

BASKET MADE FROM STAINLESS STEEL WIRE MESH

BASKET *(with stand)*

	Art. No.	outside dimension
Box	**270-390-03Y**	244 x 253 h:40 mm
	270-390-05Y	244 x 253 h:60 mm
	270-390-07Y	244 x 253 h:80 mm
	270-390-10Y	244 x 253 h:110 mm
Lid	**270-390-00Y**	ONLY LID, for baskets

The baskets which are less than 44 mm in height do not include the handles.

STAND

Art. No.	height
260-825-20Y	20 mm

STAND

Art. No.	height
260-825-14Y	10 mm

WIRE BASE

Art. No.	dimension
260-393-00Y	255 x 255 x 30 mm

TONTARRA

STANDARD MODEL

1/2 Half Size

ACCESSORIES

DRAPE RETAINER

260-395-00Y
255 x 255 mm

SILICONE MAT

260-851-00Y - green
260-851-01Y - blue
250 x 235 mm

260-852-00Y - green
260-852-01Y - blue
230 x 220 mm

SILICONE MESH MAT

260-859-00Y
250 x 240 mm

FILTER DISPENSER

260-801-00Y

SILICONE HANDLE

260-822-03Y
260-822-02Y
260-822-05Y
260-822-04Y
260-822-01Y
260-822-06Y

DISPOSABLE SINGLE USE PAPER FILTER

260-800-00Y
with steam indicator
500 pcs. /box

PTFE/TEFLON FILTER REUSABLE

260-800-03Y
Period of use approx. 2000 sterilization cycles
1 pc./box

IDENTIFICATION LABELS *(aluminium)*

260-820-03Y
260-820-04Y
260-820-05Y
260-820-02Y
260-820-01Y
260-820-06Y

LABELS *(paper)*

260-810-00Y
1000 pcs.

CERTIFICATE

This is to certify that the company

TONTARRA Medizintechnik GmbH

Daimlerstraße 15
78573 Wurmlingen
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
Development, production and sales of non-active surgical instruments and optics as well as active surgical instruments

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	448891 MP2016
Certificate unique ID	170781610
Effective date	2022-07-23
Expiry date	2024-04-26
Frankfurt am Main	2022-07-23

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

DQS IS A MEMBER OF
IQNET

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de
The validity of this certificate can only be verified by the QR-code.

410_90e Version 1.0

Annex to certificate
Certificate registration No.: 448891 MP2016
Certificate unique ID: 170781610
Effective date: 2022-07-23

TONTARRA Medizintechnik GmbH

Daimlerstraße 15
78573 Wurmlingen
Germany

Location	Scope
550871 **TONTARRA Medizintechnik GmbH** Daimlerstraße 15 78573 Wurmlingen Germany	Development, production and sales of non-active surgical instruments and optics as well as active surgical instruments
550872 **TONTARRA Medizintechnik GmbH** Max-Planck-Straße 12-16 78573 Wurmlingen Germany	Development, production and sales of non-active surgical instruments and optics as well as active surgical instruments

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Tontarra Medizintechnik GmbH

Daimlerstraße 15
78573 Wurmlingen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Sterilizable non-active surgical instruments and optics as well as active surgical instruments according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	448891 MR2
Certificate unique ID	170775468
Effective date	2021-03-11
Expiry date	2024-05-26
Frankfurt am Main	2021-03-11

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 448891 MR2
Certificate unique ID: 170775468
Effective date: 2021-03-11

Tontarra Medizintechnik GmbH

Daimlerstraße 15
78573 Wurmlingen
Germany

Device family	Device	Class
Endoscopic Instruments	Arthroscopy sheaths	IIa
	Hysteroscopy sheaths	
	Nephroscopy sheaths	
	Resectoscopy sheaths	
	Cystoscopy sheaths	
	Urethrotome sheaths	
	Resectoscopy working elements	
Monopolar and bipolar Instruments	Dismantable monopolar and bipolar coagulation forceps for MIS	IIb
	Endoor-Cut disposable tips, sterile	
	Bipolar scissors	IIb
	Bipolar forceps for MIS	IIb
	Monopolar and bipolar coagulation tweezers	IIb
	Cholangiography forceps, sterile	IIa
Optics	Arthroscope	IIa
	Hysteroscope	IIa
	Cystoscope	IIa
	Laparoscope	IIa
	Nephroscope	IIa
	Ureterorenoscope	IIa
	Ventrikuloscope	IIa
	Otoscope	IIa
	Laryngoscope, starr	IIa
Endoscopic instruments and accessoires	Trocar sleeves	IIa
	Verres needles	IIa
Electrodes	Monopolar RF electrodes	IIb
	Bipolar RF electrodes	IIb
	Sterile resectoscopy electrodes	IIb

Annex to certificate
Certificate registration No.: 448891 MR2
Certificate unique ID: 170775468
Effective date: 2021-03-11

Tontarra Medizintechnik GmbH

Daimlerstraße 15
78573 Wurmlingen
Germany

Device family	Device	Class
Suction cannulas	Monopolar suction cannulas for MIS	IIb
Suction / irrigation instruments	Suction / irrigation instruments	IIa
Retractors	Retractors, self-retaining	IIa

CERTIFICATE

This is to certify that the company

TONTARRA Medizintechnik GmbH

Daimlerstraße 15
78573 Wurmlingen
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
Design, development, manufacture and distribution of endoscopic intruments, medical endoscopes, cannulas and trocars, electrodes (monopolar & bipolar), reusable surgical instruments.
-AUS (a), BRA, CND, JPN, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	448891 MDSAP16
Certificate unique ID	1000117262
Effective date	2023-07-14
Expiry date	2026-07-13
Frankfurt am Main	2023-07-14

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, info-med@dqs.de
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.dqs.de/en/customer-database/ to validate this certificate.
The validity of this certificate can only be verified by the QR-code.

413.01 Version 6.0

Annex to certificate
Certificate registration No.: 448891 MDSAP16
Certificate unique ID: 1000117262
Effective date: 2023-07-14

TONTARRA Medizintechnik GmbH

Daimlerstraße 15
78573 Wurmlingen
Germany

Audited site	REPs FEI No.: site scope and country-specific requirements
550871 **TONTARRA Medizintechnik GmbH** Daimlerstraße 15 78573 Wurmlingen Germany	Design, development, manufacture and distribution of endoscopic intruments, medical endoscopes, cannulas and trocars, electrodes (monopolar & bipolar), reusable surgical instruments. -**AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F006777**
550872 **TONTARRA Medizintechnik GmbH** Max-Planck-Straße 12-16 78573 Wurmlingen Germany	Design, development, manufacture and distribution of endoscopic intruments, medical endoscopes, cannulas and trocars, electrodes (monopolar & bipolar), reusable surgical instruments. -**AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F006777**

Annex to certificate
Certificate registration No.: 448891 MDSAP16
Certificate unique ID: 1000117262
Effective date: 2023-07-14

TONTARRA Medizintechnik GmbH

Daimlerstraße 15
78573 Wurmlingen
Germany

Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821

EU Quality Management Certificate

This is to certify that the company

Tontarra Medizintechnik GmbH

Daimlerstraße 15
78573 Wurmlingen
Germany

SRN: DE-MF-000005520

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

Certificate registration no.	448891 MDR2017Q
Certificate ID	170779053
Effective date	2022-12-15
Expiry date	2027-12-14
Frankfurt am Main,	2022-12-15

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.

420.90 Version 4.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005520
Certificate ID: 170779053

Device categories covered by this certificate:

Device category:	**Reusable surgical Instruments**
Risk classification:	Class I (reusable)
Intended purpose:	Reusable surgical instruments for drilling, sawing, scraping, scraping, stapling, spreading, stapling or similar intended for reuse after appropriate procedures such as cleaning, disinfection and sterilization have been carried out.

Examinations and tests performed:
448891_A209802MED_02 dated 2022-010-07
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Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.
In the case of reusable surgical instruments, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing, as well as the related instructions for use.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a