Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 010066 0426 Rev. 00

Manufacturer: **AESCULAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Product Category(ies): **Implants, Instruments and Devices (for detailed information see attachment)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713159626

Valid from: 2019-07-27

Valid until: 2024-05-26

Date, 2019-07-16

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 010066 0426 Rev. 00

Facility(ies):

AESCULAP AG
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

Surgical and dental instruments
Joint implants (hip, knee)
Spinal implants
Implants for osteosynthesis
Neurosurgical vascular implants
Products for ligature
Motor systems
High frequency surgery devices
Endoscopic systems
Navigation system
Surgical suction pumps
Implants for replacement of connective tissue
Vascular prostheses and accessories
and other surgical accessories
Collagen implants

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

B|BRAUN

Quality Management
Aesculap AG
Postfach 40
D-78501 Tuttlingen
e-mail: konrad.kobel@aesculap.de
http://www.aesculap.de

Quality Inspection Certificate

Cert.-No.: 1- 010212

Aesculap AG certifies, that

our products and raw materials

Instrument-type	Steel-type	Hardness-HRC
Retractors	X20Cr13	40-48
Scissors	X50CrMoV15; X38CrMoV15	50-58
Chisel, Gouges, Curettes	X46Cr13; X20Cr13	50-58; 40-48
(Bone) Rongeure	X46Cr13	50-58
Dissecting Forceps	X15Cr13; X20Cr13	40-48
Forceps with shaft handle	X15Cr13; X20Cr13	40-48
Forceps with ring handle	X20Cr13	40-48

are designed, manufactured and tested according defined and documented specifications and procedures.

The following national and international standards and requirements were met:

☒ EN ISO 13485:2003 (AC 2009)
☒ Council Directive 93/42 EEC of 14. June 1993 concerning Medical Devices
☒ ISO 7153-1 (Surgical Instruments-Metallic materials; Part 1: Stainless steel)
☒ Others: The defined requirements and performed tests cover also corrosion analisis, cutting ability, elasticity and mechanical resistance were applicable.
Technical / physical test according to the quality specification – passes test
Chemical test according to the quality specification – passes test

AESCULAP AG

i. V.
Georg Erhard
Director Quality Management Organization

i. V.
Wolfgang Fuchs
Project Manager QM-Instruments

B|BRAUN

Declaration

The certification body of TÜV Süd Management Service GmbH and the TÜV Süd Product Service GmbH confirm that we,

AESCULAP AG
AM AESCULAP-PLATZ
78532 TUTTLINGEN / GERMANY

have established and are maintaining a quality management system according to

ISO 9001:2015
(Certificate Registration No.: 12 100 21724 TMS)
EN ISO 13485:2016
(Certificate No.: Q5 17 03 10066 408)

for the following area

Development, Production and Distribution of Implants, Instruments, Containers, Devices, Suture Material, Tissue Adhesives and Procedure Kits.

Furthermore we have implemented the conformity assessment procedure as per annex II, clause 3 of the Medical Device Directive 93/42/EEC of June 14th, 1993 for medical products.

By labeling the products

Aesculap Product Groups
as per attached list

with the CE mark

we, **AESCULAP AG** confirm,
that we follow the essential requirements
according to MDD 93/42/EEC Annex I.

TUTTLINGEN, 2018-03-13

AESCULAP AG

i. V.

Thomas Marquard
Regulatory Affairs

i. A.

Denise Hermle
Regulatory Affairs

B BRAUN

Attachment to Declaration of 2018-03-13

Aesculap Product Groups
Surgical, diagnostic and dental instruments
Joint Implants (Hip, Knee)
Spinal Implants
Implants for osteosynthesis
Neurosurgical Vascular Implants
Products for Ligature
Motor Systems
Sterilization Containers and Accessoires
Hifh Frequency Surgery Devices
Endoscopic Systems
Navigation Systems
Surgical Suction Pumps
Special Suture-Sets
Implants for Replacement of Connective Tissue
Tissue Adhesives
Vascular Prosthesis and Accessories
Local Haemostatics
Other Surgical Accessories

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www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 010066 0426 Rev. 00

Manufacturer: **AESCULAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Product Category(ies): **Implants, Instruments and Devices (for detailed information see attachment)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713159626

Valid from: 2019-07-27

Valid until: 2024-05-26

Date, 2019-07-16

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 010066 0426 Rev. 00

Facility(ies):

AESCULAP AG
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

Surgical and dental instruments
Joint implants (hip, knee)
Spinal implants
Implants for osteosynthesis
Neurosurgical vascular implants
Products for ligature
Motor systems
High frequency surgery devices
Endoscopic systems
Navigation system
Surgical suction pumps
Implants for replacement of connective tissue
Vascular prostheses and accessories
and other surgical accessories
Collagen implants

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 010066 0435 Rev. 00

Holder of Certificate: **AESCULAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Certification Mark:

Scope of Certificate: **Design and development, production, technical service and distribution of implants, instruments, instrument management systems, containers, devices, tissue adhesives**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713175266

Valid from: 2020-06-01
Valid until: 2023-05-31

Date, 2020-05-27

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 010066 0435 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

AESCULAP AG
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

AESCULAP AG
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

- Surgical and dental instruments
- Joint implants (hip, knee)
- Spinal implants
- Implants for osteosynthesis
- Neurosurgical vascular implants
- Products for ligature
- Motor systems
- Sterilization containers and accessories
- High frequency surgery devices
- Endoscopie systems
- Navigation systems
- Surgical suction pumps
- Implants for replacement of connective tissue
- Tissue adhesives
- Vascular prostheses and accessories
- Local haemostatics
- Other surgical accessories
- Collagen implants

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TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Aesculap AG

Am Aesculap-Platz, 78532 Tuttlingen, Germany
Carl-Braun-Straße 1, 34212 Melsungen, Germany

has established and applies
a Quality Management System for

Design and Development, Technical Service, Production and Distribution of Implants, Instruments, Containers, Devices, Suture Material and Tissue Adhesive

Aesculap AG Tuttlingen

- Surgical and dental instruments
- Joint Implants (hip, knee)
- Spinal Implants
- Implants for Osteosynthesis
- Neurosurgical Vascular Implants
- Motor systems
- Sterilization containers and accessories
- High frequency surgery devices
- Endoscopie systems
- Navigation systems
- Surgical suction pumps
- Veterinary instrumentation
- Other surgical accessories
- Instrument Management System
- Collagen implants

Aesculap AG Melsungen

- Implants for replacement of connective tissue
- Tissue adhesive
- Local haemostatic

An audit was performed, Order No. **70062209**.

Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2020-06-01** until **2023-05-31**.

Certificate Registration No.: **12 100 21724 TMS**.

Product Compliance Management
Munich, 2020-05-20

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS/01-01/2019

DECLARATION OF CONFORMITY

1) Manufacturer

Wexler Surgical, Inc.
11333 Chimney Rock Road
Houston, Texas 77035 USA

2) European authorized representative:

CEpartner4U BV
Esdoornlaan 13
3951 DB Maarn
Netherlands

3) Product(s)

Device category: *Reusable instruments, non-sterile and accessoiries*
Device groups: *Forceps, Surgical Cutting Instruments, Surgical Suction Instruments*

4) The product(s) described above is in conformity with:

Title	Document No.
Medical Device Directive	93/42/EEC

5) Additional information *(conformity procedure, Notified Body, CE certificate, Registration nr., etc.)*:

Conformity assessment procedure for CE marking: Medical Device Directive, Annex VII

Device risk classification: Class I (Rule 6)

Houston, Texas; 2021-06-03

Kimberly Hernandez, RA/QA Manager

Appendix

Date: 2021-06-03

Surgical Suction Instruments	Madani PTE Suction	AL1170.1	To aspirate fluids from the surgical site	Class I, Rule 6 (2nd Indent)	12/1/2014
Surgical Suction Instruments	Madani PTE Suction	AL1172.1	To aspirate fluids from the surgical site	Class I, Rule 6 (2nd Indent)	12/1/2014
Surgical Cutting Instrument	Micro Dissector	DL9101.2	To cut specific tissue or vessels	Class I (Rule 6)	6/30/2000
Forceps	Madani DeBakey Forceps	FL6025.2	To hold tissue or anatomic structures	Class I (rule 6)	6/17/2013
Forceps	Double-Action DeBakey Forceps	FL6035.2	To hold tissue or anatomic structures	Class I (rule 6)	1/9/2011

Orion Registrar, Inc.

Thorough and Fair Auditing

Certificate of Certification

This is to certify the Quality Management System of:

Wexler Surgical, Inc.

11333 Chimney Rock Road, Suite 110
Houston, TX 77035 USA

Has been assessed by Orion Registrar and found to be in compliance with the following Quality Standard:

ISO 13485:2016

The Quality Management System is applicable to:

Distribution of Surgical Devices including: Relabeling and Repackaging, Developing Specifications

The Certification period is from

January 21, 2020 to February 17, 2023

This certification is subject to the company maintaining its system to the required standard, and applicable exceptions, which will be monitored by Orion.

Client ID: 1724 Certificate ID: 1018028

ANAB ACCREDITED ISO/IEC 17021-1 MANAGEMENT SYSTEMS CERTIFICATION BODY

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

Paul M. Burck, President — January 21, 2020 Date

7502 W. 80th Avenue, Suite 225, Arvada, Colorado 80003 | 303-456-6010 | FAX 303-456-6681 | www.orion4value.com

To authenticate this certificate, please visit: www.orion4value.com/about-orion/registered-companies/

FEHLING INSTRUMENTS

Fehling Instruments GmbH & Co. KG
Hanauer Landstr. 7A
D-63791 Karlstein/Germany
Phone: +49 (0) 61 88 - 95 74-0
Fax: + 49 (0) 61 88 - 95 74-46

FEHLING INSTRUMENTS GmbH & Co.KG • Hanauer Landstr. 7A • 63791 Karlstein

01. June 2021 / UM
info@fehling-instruments.de
www.fehling-instruments.de

CERTIFICATE OF COMPLIANCE

We hereby confirm that the article MRD-7 manufactured by FEHLING INSTRUMENTS GmbH & Co. KG is manufactured in correspondence with the following norms:

DIN 13111:2018	DIN 58280:2016	DIN 96298-3:2017	DIN EN ISO 11139:2019
DIN 13112-1:2017	DIN 96015:2016	DIN 96042:2006	DIN ISO/TS 15883-5:2006
DIN 13114-1:2013	DIN 96105:2010	DIN 96110:2006	ISO 7741:1986
DIN 13451:2017	DIN 96114:2010	DIN EN ISO 16061:2015	BS 5194-4:1986
DIN 13452:2017	DIN 58282:2017	DIN EN ISO 7153-1:2017	DIN EN ISO 15798:2018
DIN 58252-1:2017	DIN 58281-1:2017	DIN EN ISO 14607:2018	DIN EN ISO 25539-1:2018
DIN 13990:2017	DIN 58270:2017	DIN EN ISO 5840-2:2016	DIN EN ISO 10993-6:2017
DIN 58253-1:2014	DIN 58300:2014	DIN EN 62570:2016	DIN EN ISO 16671:2018
DIN 58254:2017	DIN 96298-1:2016	DIN EN 13718-2:2015	DIN EN ISO 10993-4:2017
DIN 58279:2006	DIN 96298-2:2016	DIN EN ISO 22674:2016	DIN EN ISO 16672:2015
DIN EN ISO 14971:2013	DIN EN ISO 14971:2013		

Karlstein, June 01, 2021

FEHLING INSTRUMENTS GmbH & Co. KG

FEHLING INSTRUMENTS GmbH & Co. KG
Hanauer Landstr. 7A
63791 Karlstein/Germany
Phone: +49(0)61 88-95 74-40
Fax: +49(0)61 88-95 74-45

Ulrike Maschke
-Quality Management/R&D-

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

FEHLING INSTRUMENTS GmbH & Co. KG

Hanauer Landstraße 7A
63791 Karlstein
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:

Sterile and non-sterile, non-active cervical spine implants, sterile and non-sterile, non-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.	099980 MR2
Certificate unique ID	170734114
Effective date	2019-03-29
Expiry date	2021-07-24
Frankfurt am Main	2019-03-29

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.: 099980 MR2
Certificate unique ID: 170734114
Effective date: 2019-03-29

FEHLING INSTRUMENTS GmbH & Co. KG

Hanauer Landstraße 7A
63791 Karlstein
Germany

Device family	Device	Class
Cervical spine implants	FENESTRA – Cervicale Cages, unsterile FENESTRA – Cervicale Cages, sterile FORMAR – Cervicale Cages, unsterile FORMAR – Cervicale Cages, sterile	IIb
Single use sterile instruments	Single use biopsy forceps in different lengths and widths. Single use osteobioptomes in different widths VERTECT – Jack device MANNHEIM – Galea-hook	IIa
Instruments	CALAFIORE sternal retrainer Retractors/Retainers/Spreaders (fixed/self-retaining)	IIa IIa

FEHLING
INSTRUMENTS

KONFORMITÄTSERKLÄRUNG / Declaration of conformity

Wir / We

FEHLING INSTRUMENTS GmbH & Co. KG
Hanauer Landstr. 7A, 63791 Karlstein, Germany

erklären in alleiniger Verantwortung, dass
declare on our own responsibility that

die Medizinprodukte the medical devices	Scheren Scissors
	Artikelnummern: siehe Anlage Item numbers: see annex
Klassifizierung gemäß MDD: Classification according to MDD:	Klasse I gemäß Regel 6 Class I according to rule 6

allen Anforderungen der Richtlinie 93/42/EWG entsprechen.
meet all the provision of the Directive 93/42/EEC which apply to them.

Angewandte harmonisierte Normen: Applied harmonized standards:	EN ISO 15223-1:2017 EN 1041:2013 EN 62366-1:2017 EN ISO 10993-1:2010 EN ISO 13485:2016 EN ISO 14971:2013 EN ISO 17664:2018
Andere normative Dokumente: Other normative documents:	MEDDEV Guidelines ./.
Laufzeit der Erklärung: Period of validity:	bis 2020-05-26 until 2020-05-26
Konformitätsbewertungsverfahren: Conformity assessment procedure:	Anhang VII der Richtlinie 93/42/EWG Annex VII of the Directive 93/42/EEC

Karlstein, 2018-11-30

Ort, Datum / place, date

Esther Bauer
QM-Beauftragte / Quality management

Name, Funktion, Unterschrift
Name, function, signature

ID: 29-001

KONFORMITÄTSERKLÄRUNG
Declaration of conformity

Anhang / Annex

FEHLING INSTRUMENTS

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BAA-6
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BAC-1
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BAD-1
BAD-2
BAD-3
BAD-4
BAD-5
BAD-6
BAD-7
BAD-8
BAD-9
BAE-1
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Artikel-Nr. Item No.
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BAF-8
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BAG-1
BAG-2
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BAU-1
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BAV-8
BAV-9
BAW-0
BAW-1
BAW-7
BAX-3
BAX-4
BAY-2
BAY-4
BAY-5
BAZ-8
BAZ-9
BBA-0
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BBA-4
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Artikel-Nr. Item No.
BBB-4
BBB-5
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BBC-1
BBC-2
BBC-3
BBC-4
BBC-6
BBC-7
BBC-8
BBC-9
BBD-2
BBD-3
BBD-4
BBD-5
BBD-6
BBD-7
BBD-7+
BBD-8
BBD-9
BBE-1
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BBE-5
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BBM-0
BBN-0
BBN-7
BBN-8

Artikel-Nr. Item No.
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BBO-1B
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BBP-9
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BBR-2
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BBT-2
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BBU-9
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BBV-3
BBV-4
BBX-0
BBX-1
BBX-2
BBX-7
BBY-1
BBY-2
BBY-3
BBY-4
BBY-5
BBY-8
BBY-9
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Artikel-Nr. Item No.
BBZ-8
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BCA-1
BCA-2
BCA-5
BCA-6
BCA-7
BCA-8
BCB-3
BCB-4
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BCB-6
BCB-7
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BCD-3
BCD-4
BCD-5
BCD-8
BCE-0
BCG-3
BCG-4
BCG-5
BCG-6
BCG-8
BCH-3
BCH-6

KONFORMITÄTSERKLÄRUNG
Declaration of conformity

Anhang / Annex

FEHLING INSTRUMENTS

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BCJ-6
BCJ-7
BCK-6
BCK-8
BCL-3
BCL-4
BCL-5
BCL-6
BCL-7
BCL-9
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BCN-7
BCN-8
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BCO-1
BCO-3
BCO-4
BCO-5
BCO-6
BCO-7
BCR-1
BCR-2
BCS-1
BCS-2
BCT-2
BCU-6
BCY-3
BCY-9
BDA-4
BDC-9
BDD-0
BDF-0
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BDG-5
BDH-4

Artikel-Nr. Item No.
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BOA-1
BOA-2
BOA-2S
BOA-3
BOA-3+
BOA-3S
BOA-4
BOA-4S
BOA-5
BOA-6
BOA-7
BOA-7+
BOA-8
BOB-0
BOB-1
BOB-1+
BOB-1B
BOB-1S
BOB-2
BOB-3
BOB-3+
BOB-3T
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BOB-8+
BOB-9
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BOC-1+
BOC-1S
BOC-2
BOC-2+
BOC-2S
BOC-3

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BOC-4+
BOC-4S
BOC-5
BOC-5+
BOC-6
BOC-6S
BOD-1
BOD-2
BOD-2+
BOD-3
BOD-4
BOD-5
BOD-5+
BOD-6
BOD-7
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BOE-1
BOE-1+
BOE-1S
BOE-2+
BOE-2S
BOE-3
BOE-3+
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BOE-4+
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BOE-5S
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BOE-8
BOF-0
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BOM-9
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BON-3
BON-3S
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BOZ-0
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KONFORMITÄTSERKLÄRUNG
Declaration of conformity

Anhang / Annex

FEHLING INSTRUMENTS

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BRA-7
BRA-7L
BRA-8
BRA-8L
BRA-9
BRA-9L
BRB-0
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BRW-1
BRW-2
BRW-5
BRX-0
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BRX-2
BRX-2C
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BRX-5
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BRZ-7
BRZ-8
BRZ-9
BSA-0
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BSA-3
BSA-4
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BSA-6
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BSC-1
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BSD-2T
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BSD-4
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BSK-0
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KONFORMITÄTSERKLÄRUNG
Declaration of conformity

Anhang / Annex

FEHLING INSTRUMENTS

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BSL-0
BSL-0T
BSL-0U
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BSM-1T
BSM-1U
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BSM-2+
BSM-2S
BSM-2T
BSM-2U
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BSM-3S
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BSM-3U
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BSN-5S
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BSP-1
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BSP-1T
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BSP-2S
BSP-2T
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BZA-6
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BZC-8
BZC-9
BZD-1
BZE-1
BZE-1C
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MRC-6D
MRC-7
MRC-8
MRD-6
MRD-7
MRD-7L
MRM-0
MRM-3
MRQ-0
MRQ-4
MRQ-4C
MRT-2
MRT-3
MRT-3M
MRT-5
MSO-2
MSO-3
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MSO-9
MSP-1D
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TOR-0
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ZCH-2
ZOC-6
ZOC-6

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Holds Certificate No: **FM 575411**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, development, manufacture, warehousing, distribution, installation and maintenance of ophthalmo-surgical instruments, active device systems and associated accessories, implants, sterilisation trays and containers.
Warehousing and distribution of gases, silicone oils, dyes, perfluorocarbons and semifluorinated alkanes for ophthalmology.

For and on behalf of BSI:

Andrew Launn, EMEA Systems Certification Director

Original Registration Date: 2001-06-01
Latest Revision Date: 2020-05-18

Effective Date: 2020-05-26
Expiry Date: 2023-05-25

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EC Certificate - Full Quality Assurance System

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

No. **CE 575415**

Issued To: **Geuder AG**
Hertzstraße 4
69126 Heidelberg
Germany

In respect of:

See certificate scope page.

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: **2016-06-29** Date: **2020-08-10** Expiry Date: **2024-05-25**

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Certificate No: CE 575415

Certificate Scope:

Design, development and manufacture of devices for ophthalmology: Ultrasonic Handpieces; Single-Use Light Conductors / Fiber Optics, sterile; Fiber Optic Instruments, reusable; Single-Use Accessory Kits with Ultrasonic Tips, sterile; Ultrasonic tips, reusable; Single-Use Vitrectomy Instruments, sterile; Single-Use DMEK Cartridge, sterile; Single-Use-DMEK-Transportation Cartridge, sterile; Sclera Pins; Single-Use Iris Retractor, sterile; Vitrectomy Infusion Tube and Cutting Heads; Single-Use Trocar System, sterile; Single-Use Ophthalmic Cannula; Injection-/Infusion Tubing; Single-Use Tubing Sets, sterile; Tubing Sets, reusable; Cassettes; Single use vitreous cutters, sterile; Single-Use Vitrectors, sterile; Single-use LED Lightsource, sterile; Single-Use Silicone Implants, sterile.
Those aspects of Annex II related to sterility in the design, development and manufacture of devices for ophthalmology: Single-Use Adapters, sterile; I/A Instruments, sterile.

Auslegung, Entwicklung und Herstellung von Produkten für die Ophthalmologie: Ultraschallhandgriffe; Einmal-Lichtleiter, steril; Kaltlichtinstrumente, wiederverwendbar; Einmal-Kits mit Ultraschallspitzen, steril; Ultraschallspitzen, wiederverwendbar; Einmal-Vitrektomiespitzen, steril; Einmal-DMEK-Kartusche, steril; Einmal-DMEK-Transportkartusche, steril; Skleranägel; Einmal-Irisretraktor, steril; Vitrektomie Infusionsrohr und Schneideköpfe; Einmal-Trokarsystem, steril; ophthalmologische Einmal-Kanülen; Injektions- / Infusionshalterungen; Einmal-Schlauchsysteme, steril; Schlauchsysteme, wiederverwendbar; Kassetten; Einmal-Vitrektoren, steril; Einmal-LED Lichtquellen, steril; Einmal-Silikonimplantate, steril.
Die Aspekte des Anhangs II im Zusammenhang mit der Sterilität bei der Auslegung, Entwicklung und Herstellung von Einmal-Adaptern für Glasspritzen, steril; Spül- und Sauginstrumenten, steril.

First Issued: **2016-06-29** Date: **2020-08-10** Expiry Date: **2024-05-25**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 575415

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
Class IIb		
MD 1105	Ultrasonic Handpieces	Used with ultrasound tips to perform phacoemulsification, a surgical procedure that uses ultrasonic energy to fragment (or emulsify) a cataractous lens and removes the lens material through a small incision.
MD 0105	Single-use Silicone Implants, sterile	For use on the sclera to aid in retinal reattachment.
Class IIa		
MD 0105	Single-use Light Conductors / Fiber Optics, sterile	For endoillumination during vitreoretinal surgery, allowing the surgeon to see intraocular details and lesions in the anterior and posterior segment of the eye.
MD 0105	Single-use Light Conductors / Fiber Optics, sterile, incl. Uno Colorline	For endoillumination during vitreoretinal surgery, allowing the surgeon to see intraocular details and lesions in the anterior and posterior segment of the eye.

First Issued: **2016-06-29** Date: **2020-08-10** Expiry Date: **2024-05-25**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 575415

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0105	Fiber Optic Instruments, reusable	For endoillumination during vitreoretinal surgery, allowing the surgeon to see intraocular details and lesions in the anterior and posterior segment of the eye.
MD 0105	Single-use Accessory Kits with Ultrasonic Tips, sterile	Accessories and tips to be used with US-handpieces to perform phacoemulsification.
MD 0105	Ultrasonic tips, reusable	US tips to be used with US-handpieces to perform phacoemulsification.
MD 0105	Single-use Vitrectomy Instruments Uno Colorline, sterile	For manipulation and crushing of intraocular tissue during pars plana vitrectomy. For usage in the posterior eye segment for cutting and gripping of ocular structures.
MD 0102	Single-use DMEK Cartridge, sterile	Used for Descemet Membrane Endothelial Keratoplasty, a special technique for corneal transplantation. For uploading and injecting descemet membrane transplant.
MD 0102	Single-use DMEK Transportation Cartridge, RAPID	Used for Descemet Membrane Endothelial Keratoplasty, a special technique for corneal transplantation. For uploading, transporting and injecting descemet membrane transplant.

First Issued: **2016-06-29** Date: **2020-08-10** Expiry Date: **2024-05-25**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 575415

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0105	Sclera Pins	To be used to occlude temporarily the exterior points of access (incisions) during surgeries in the posterior segment to minimize leakages of liquid or gases.
MD 0105	Single-use Iris Retractor, sterile	To be used dilate the iris mechanically.
MD 0105	Mega-Vit Vitrectomy Infusion Tube and Cutting Heads	Accessories to use with high speed drive for cutting and intraocular removal of the vitreous body.
MD 0105	Single-use Trocar System Uno Colorline, sterile	To open and keep the scleral incision (in the area of pars plana) in open state, so to allow access of different ophthalmic surgical instruments to the inside of the eye.

First Issued: **2016-06-29** Date: **2020-08-10** Expiry Date: **2024-05-25**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 575415

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102	Single-use Ophthalmic Cannula	Used to supply or remove liquids such as saline solution (BSS), viscous liquids, PFCL, air or gases. Capsule polishing needles or vacuum cleaner needles with silicone tip can also be used to remove tissue or materials.
MD 0102	Injection/Infusion Tubing	Infusion Tubing: applying liquids and air. Injection tubing: applying viscous solutions into eyes in vitreoretinal surgery.
MD 0102	Single-use Tubing Sets, sterile	Irrigation and aspiration of aqueous solutions, air injections and silicone oil into the eve.
MD 0102	Tubing Sets, reusable	For irrigation and aspiration of aqueous solutions, air injections and silicone oil into the eye.
MD 0102	Cassettes	Connected to the ophthalmic system for irrigation and aspiration.
MD 1105	Single-use vitreous cutters, sterile	For removal of vitreous body from the eye.

First Issued: **2016-06-29** Date: **2020-08-10** Expiry Date: **2024-05-25**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 575415

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1105	Single-use Vitrectors, sterile, Uno Colorline	For removal of vitreous body from eye.
MD 1105	OcuLED Single-use LED Lightsource, sterile	For endoillumination during ocular surgery.
Class Is		
MD 0105	Single-use Adapters, sterile	Used during the pneumatic injection of silicone oil into the eyes of patients. It is a protective holder for the glass syringes that are filled with silicone oil or viscous fluids. It is to prevent injuries in case the glass syringe breaks under the pressure.
MD 0102	I/A Instruments, sterile	Used in ophthalmological surgery, to remove liquids and tissue from the eye and irrigate the eye with air or balanced saline solution (BSS).

First Issued: **2016-06-29** Date: **2020-08-10** Expiry Date: **2024-05-25**

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 575413**

Issued To: **Geuder AG**
Hertzstraße 4
69126 Heidelberg
Germany

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2016-06-29** Date: **2019-05-24** Expiry Date: **2024-05-25**

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By Royal Charter

Certificate No: CE 575413

Certificate Scope:

Manufacture of ophthalmic Single-Use Light Conductors / Fiber Optics, sterile; Single-Use Ophthalmic Cannula, sterile; Single-Use Tubing Sets, sterile; Irrigation/Aspiration (I/A) Instruments, sterile; Single-use Endo-probes, sterile; Single-use Knives, sterile; Single-use Trephines, sterile.
Those aspects of Annex V related to sterility in the manufacture of Bonn Injection Sets for ophthalmology.
Those aspects of Annex V related to metrology in the manufacture of ophthalmic surgical measuring devices.

Herstellung von ophthalmologischen Einmal-Lichtleitern, steril; ophthalmologischen Einmal-Kanülen, steril; Einmal-Schlauchsystemen, steril; Spül- und Sauginstrumenten, steril; Einmal-Endosonden, steril; Einmal-Messern steril; Einmal-Trepanen, steril.
Die Aspekte des Anhangs V im Zusammenhang mit der Sterilität bei der Produktion Bonner Injektonssets, steril.
Die Aspekte des Anhangs V im Zusammenhang mit der Messfunktion bei der Produktion der ophthalmologischen Messinstrumente.

First Issued: **2016-06-29** Date: **2019-05-24** Expiry Date: **2024-05-25**

EC Certificate - Production Quality Assurance

Supplementary Information to CE 575413

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0105	Single-use Light Conductors / Fiber Optics, sterile	For endoillumination during vitreoretinal surgery, allowing the surgeon to see intraocular details and lesions in the anterior and posterior segment of the eye.
MD 0102	Single-use Ophthalmic Cannula, sterile	Used to supply or remove liquids such as saline solution (BSS), viscous liquids, PFCL, air or gases. Capsule polishing needles or vacuum cleaner needles with silicone tip can also be used to remove tissue or materials.
MD 0102	Single-use Tubing Sets, sterile	Irrigation and aspiration of aqueous solutions, air injections and silicone oil into the eye.
MD 0102	Irrigation/Aspiration (I/A) Instruments, sterile	Used in ophthalmological surgery, to remove liquids and tissue from the eye and irrigate the eye with air or balanced saline solution (BSS).
MD 0105	Single-use Endoprobes Uno Colorline, sterile	To direct and localize the transmission of laser output energy to the operative site in the ophthalmic surgical field. The laser is used to finely coagulate ocular tissue.

First Issued: **2016-06-29** Date: **2019-05-24** Expiry Date: **2024-05-25**

EC Certificate - Production Quality Assurance

Supplementary Information to CE 575413

Issued To:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0105	Single-use Knives, sterile	To make surgical cuts in ophthalmological surgery.
MD 0105	Single-use Trephines, sterile	Used for preparing the donor cornea for transplantation.
Class Is		
MD 0105	Bonn Injection Set, sterile	Used to inject medications intravitreally. The medications do not come with the set.
Class Im		
MD 0104	Measuring Instruments	Instruments for length and angle measurements in ophthalmology.

First Issued: **2016-06-29** Date: **2019-05-24** Expiry Date: **2024-05-25**

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Geuder AG
Hertzstraße 4
69126 Heidelberg
Germany

Holds Certificate Number: **MD 575412**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-06-27
Latest Revision Date: 2020-05-18

Effective Date: 2020-05-26
Expiry Date: 2023-05-25

...making excellence a habit.™

Certificate No: **MD 575412**

Registered Scope:

Design, development, manufacture, warehousing, distribution, installation and maintenance of active and non active, sterile and non sterile ophthalmic surgical devices/systems, instruments and accessories, ophthalmic implants, sterilization trays and containers.
Warehousing and distribution of silicone oils, dyes, perfluorocarbons and semifluorinated alkanes for use as liquid intraocular endotamponades and gas-based intraocular tamponades and vitreous substitutes for the area of ophthalmology.
Auslegung, Entwicklung, Produktion, Lagerhaltung, Vertrieb, Installation und Instandhaltung von aktiven und nicht aktiven, sterilen und nicht sterilen ophthalmo-chirurgischen Geräten/Systemen, Instrumenten und Zubehör, ophthalmologischen Implantaten, Sterilisationsbehältern und Sterilisationscontainern.
Lagerhaltung und Vertrieb von Silikonölen, Färbemitteln, Perfluorcarbonverbindungen und semiflourierten Alkanen für die Verwendung als flüssige intraokulare Endotamponaden, gasförmige intraokulare Tamponaden und Glaskörperersatzstoffe im Einsatzbereich der Ophthalmologie.

Original Registration Date: 2016-06-27
Effective Date: 2020-05-26
Latest Revision Date: 2020-05-18
Expiry Date: 2023-05-25

AST-Medical

AST-Medical S.R.L
R.Moldova, mun.Chișinău, MD-2044
str. Alecu Russo, 59/4, tel/fax: 022 601 102
email: astmed@yahoo.com

Către IMSP Spitalul Clinic Republican
„Timofei Moșneaga”

În atenția Grupului de lucru
al LD nr. ocds-b3wdp1-MD-1621941439948,
ID: 21040002 din 15.06.2021

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 7 zile de la solicitarea autorității contractante pentru produsele oferite în cadrul LD nr. ocds-b3wdp1-MD-1621941439948, ID: 21040002 privind achiziționarea ***Instrumentarului chirurgical pentru anul 2021.***

Cu respect,
Director Vladimir Roibu

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

FIRMA "AST-MEDICAL" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de indentificare de stat - codul fiscal

1003600132970

Data înregistrării **01.03.1999**

Data eliberării **12.02.2005**

Bobeica Ion, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

Semnătura

CAMERA ÎNREGISTRĂRII DE STAT 102

MD 0022782

L.Ş.

AST-Medical

AST-Medical S.R.L
R.Moldova, mun.Chişinău, MD-2044
str. Alecu Russo, 59/4, tel/fax: 022 601 102
email: astmed@yahoo.com

Către IMSP Spitalul Clinic Republican
„Timofei Moșneaga”

În atenția Grupului de lucru
al LD nr. ocds-b3wdp1-MD-1621941439948,
ID: 21040002 din 15.06.2021

Prin prezenta, declarăm că instrumentele chirurgicale oferite în cadrul LD nr. ocds-b3wdp1-MD-1621941439948, ID: 21040002 vor fi livrate în ambalaj original, securizat, marcat şi etichetat de producător, fără preambalare, cu date de identitate (denumirea, numărul lotului, seria, codul de referință), iar termenul de garanție la momentul livrării va constitui 12 luni.

Cu respect,
Director Vladimir Roibu