

Úradný preklad

Sworn Translation

Prekladateľ: Mgr. Tomáš Dobrotka Riečna 17 971 01 Prievidza Evidenčné číslo: 971273	Translator: Mgr. Tomáš Dobrotka Riečna 17 971 01 Prievidza Registration number: 971273
Zadávateľ: Inštitút jazykov a vzdelávania, s.r.o. Národná 18 010 01 Žilina	Ordered by: Inštitút jazykov a vzdelávania, s.r.o. Národná 18 010 01 Žilina
Úradný preklad z anglického jazyka do slovenského jazyka	Sworn translation from English language into Slovak language
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Declaration

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

AESCLAP AG
AM AESCLAP-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 010066 0435 Rev. 00)

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 VII or per annex II, clause 3 of the Medical Device Directive 93/42/EEC
of June 14th, 1993 for medical products (TÜV EC-Certificate No.: G1 010066 0426 Rev. 00 or
MEDCERT EC-Certificate No.: 7400GB410200310).


By labeling the products
as per attached list
with the CE mark

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

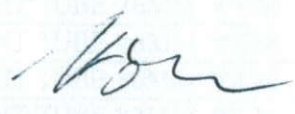
TUTTLINGEN, 2021-11-23

AESCLAP AG

i. V.


Dr. Jennifer Grünow
Global Regulatory Affairs

i. A.


Nadine Krämer
Global Regulatory Affairs

Attachment to Declaration of 2021-11-24

Article No.	Description	Risk Class Acc. To MDD 93/42
1066021	LYOPLANT 6X14CM	III
1066030	LYOPLANT 8X9CM	III
1066048	LYOPLANT 4X10CM	III
1066050	LYOPLANT 5X6CM	III
1066064	LYOPLANT 4X5CM	III
1066080	LYOPLANT 2X10CM	III
1066102	LYOPLANT 1.5X3CM	III
1066242	LYOPLANT 6X8CM	III
1067010	LYOPLANT ONLAY 2.5X2.5CM	III
1067020	LYOPLANT ONLAY 5.0X5.0CM	III
1067030	LYOPLANT ONLAY 2.5X7.5CM	III
1067040	LYOPLANT ONLAY 7.5X7.5CM	III
1067050	LYOPLANT ONLAY 10.0X12.5CM	III
1101013	UNI-GRAFT K DV STRAIGHT TUBE 08MM 15CM	III
1101021	UNI-GRAFT K DV STRAIGHT TUBE 06MM 15CM	III
1101048	UNI-GRAFT K DV STRAIGHT TUBE 07MM 15CM	III
1101102	UNI-GRAFT K DV STRAIGHT TUBE 10MM 15CM	III
1101129	UNI-GRAFT K DV STRAIGHT TUBE 12MM 15CM	III
1101137	UNI-GRAFT K DV STRAIGHT TUBE 12MM 30CM	III
1101145	UNI-GRAFT K DV STRAIGHT TUBE 14MM 15CM	III
1101161	UNI-GRAFT DV STRAIGHT 16MM, 15CM	III
1101188	UNI-GRAFT DV STRAIGHT 18MM, 15CM	III
1101200	UNI-GRAFT DV STRAIGHT 20MM, 15CM	III
1101226	UNI-GRAFT DV STRAIGHT 22MM, 15CM	III
1101242	UNI-GRAFT DV STRAIGHT 24MM, 15CM	III
1101269	UNI-GRAFT K DV STRAIGHT TUBE 06MM 40CM	III
1101277	UNI-GRAFT K DV STRAIGHT TUBE 07MM 40CM	III
1101285	UNI-GRAFT K DV STRAIGHT TUBE 08MM 40CM	III
1101307	UNI-GRAFT K DV STRAIGHT TUBE 10MM 40CM	III
1102060	UNI-GRAFT K DV STRAIGHT TUBE 06MM 30CM	III
1102079	UNI-GRAFT K DV STRAIGHT TUBE 07MM 30CM	III
1102087	UNI-GRAFT K DV STRAIGHT TUBE 08MM 30CM	III
1102109	UNI-GRAFT K DV STRAIGHT TUBE 10MM 30CM	III
1102192	UNI-GRAFT K DV STRAIGHT TUBE 26MM 30CM	III
1102206	UNI-GRAFT K DV STRAIGHT TUBE 28MM 30CM	III
1102214	UNI-GRAFT K DV STRAIGHT TUBE 30MM 30CM	III
1102222	UNI-GRAFT K DV STRAIGHT TUBE 32MM 30CM	III
1102230	UNI-GRAFT K DV STRAIGHT TUBE 34MM 30CM	III

PV010	AESULAP AEOS	IIa
PV631	EV3.0 CAMERA HEAD 0°	IIa
PV632	EV3.0 CAMERA HEAD 30°	IIa
PV641SU	SINGLE USE COVER FOR CAMERA HEAD 0°	IIa
PV642SU	SINGLE USE COVER FOR CAMERA HEAD 30°	IIa
RT043R	UNITRAC CO2 CARTRIDGE ADAPTER	IIa
RT044SU	UNITRAC CO2 CARTRIDGE	IIa
S66863	INGE LAMINECTOMY RETRACTOR	IIa
S76017	CESPACE PEEK TRIAL IMPL. 5°14X4MM MODIF.	IIa
S76018	CESPACE PEEK TRIAL IMPL. 5°14X5MM MODIF.	IIa
S76019	CESPACE PEEK TRIAL IMPL. 5°14X6MM MODIF.	IIa
S76020	CESPACE PEEK TRIAL IMPL. 5°14X7MM MODIF.	IIa
S76021	CESPACE PEEK TRIAL IMPL.5°14X8MM MODIF.	IIa
S76022	CESPACE PEEK TRIAL IMPL. 5°16X4MM MODIF.	IIa
S76023	CESPACE PEEK TRIAL IMPL.5° 16X5MM MODIF.	IIa
S76024	CESPACE PEEK TRIAL IMPL. 5°16X6MM MODIF.	IIa
S76025	CESPACE PEEK TRIAL IMPL.5° 16X7MM MODIF.	IIa
S76026	CESPACE PEEK TRIAL IMPL.5° 16X8MM MODIF.	IIa
S76027	CESPACE PEEK INSERTION ROD 4-8 MM/FJ415R	IIa
SC410R	QUINTEX FIXATION PIN NONSTERILE	IIa
SC421R	QUINTEX CALIPER	IIa
SC422R	QUINTEX FIXATION PIN INSTRUMENT	IIa
SC423R	QUINTEX ADJUSTABLE SINGLE DRILL GUIDE	IIa
SC424R	QUINTEX ADJUSTABLE DOUBLE DRILL GUIDE	IIa
SC425R	QUINTEX FIXED SINGLE DRILL GUIDE 14MM	IIa
SC426R	QUINTEX FIXED DOUBLE DRILL GUIDE 14MM	IIa
SC430R	QUINTEX DRILL BIT D2.9MM	IIa
SC432R	QUINTEX SCREW DRIVER	IIa
SC433R	QUINTEX SCREW REMOVAL TOOL	IIa
SC450	QUINTEX INSTRUMENTATION	IIa
SJ210R	PROSPACE PEEK INSERTION INSTRUMENT	IIa
SJ211R	PROSPACE PEEK IMPACTOR	IIa
SJ217P	PROSPACE SPACER PEEK/RADIOLUCENT 7MM	IIa
SJ218P	PROSPACE SPACER PEEK/RADIOLUCENT 8MM	IIa
SJ219P	PROSPACE SPACER PEEK/RADIOLUCENT 9MM	IIa
SJ220P	PROSPACE SPACER PEEK/RADIOLUCENT 10MM	IIa
SJ221P	PROSPACE SPACER PEEK/RADIOLUCENT 11MM	IIa
SJ222P	PROSPACE SPACER PEEK/RADIOLUCENT 12MM	IIa
SJ223P	PROSPACE SPACER PEEK/RADIOLUCENT 13MM	IIa
SJ231P	PROSPACE PEEK IMPLANT 0° 8X8X22MM	IIb
SJ232P	PROSPACE PEEK IMPLANT 0° 7X8X19MM	IIb
SJ233P	PROSPACE PEEK IMPLANT 0° 9X8X19MM	IIb
SJ234P	PROSPACE PEEK IMPLANT 0° 7X8X22MM	IIb

Vyhlásenie

Certifikačný orgán spoločnosti TÜV Süd Management Service GmbH a spoločnosť TÜV Süd Product Service GmbH potvrdzujú, že spoločnosť

AESULAP AG
AM AESULAP-PLATZ
78532 TUTTLINGEN / NEMECKO

vytvorila a vedie systém riadenia kvality podľa noriem

ISO 9001:2015
(reg. č. osvedčenia: 12 100 21724 TMS)
EN ISO 13485:2016
(č. osvedčenia: Q5 010066 0435 Rev. 00)

pre túto oblasť

**vývoj, výroba a distribúcia implantátov, nástrojov, nádob, zariadení, materiálov na chirurgické
zošívanie, tkanivových náplastí a sád na chirurgické zákroky.**

Okrem toho sme zaviedli postup posudzovania zhody
podľa prílohy VII alebo podľa prílohy II, odsek 3 smernice Rady č. 93/42/EHS o zdravotníckych
pomôckach zo 14. júna 1993 (TÜV Osvedčenie o zhode ES č.: G1 010066 0426 Rev. 00 alebo MEDCERT
Osvedčenie o zhode ES č.: 7400GB410200310).

Označovaním výrobkov
podľa zoznamu v prílohe
značkou CE

my, spoločnosť **AESULAP AG**, potvrdzujeme,
že dodržiavame základné požiadavky
smernice Rady č. 93/42/EHS o zdravotníckych pomôckach príloha I.

TUTTLINGEN 23.11.2021

AESULAP AG

V. Z.

(nečitateľný podpis)
Dr. Jennifer Grünow
Global Regulatory Affairs

V. Z.

(nečitateľný podpis)
Nadine Krämer
Global Regulatory Affairs

Č. výrobku	Opis	Riziková trieda podľa SZP 93/42
1066021	LYOPLANT 6X14CM	III
1066030	LYOPLANT 8X9CM	III
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1102222	UNI-GRAFT K DV STRAIGHT TUBE 32MM 30CM	III
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PV010	AESULAP AEOS	Па
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PV632	EV3.0 CAMERA HEAD 30°	Па
PV641SU	SINGLE USE COVER FOR CAMERA HEAD 0°	Па
PV642SU	SINGLE USE COVER FOR CAMERA HEAD 30°	Па
RT043R	UNITRAC C02 CARTRIDGE ADAPTER	Па
RT044SU	UNITRAC C02 CARTRIDGE	Па
S66863	INGE LAMINECTOMY RETRACTOR	Па
S76017	CESPACE PEEK TRIAL IMPL. 5U4X4MM MODIF.	Па
S76018	CESPACE PEEK TRIAL IMPL. 5U4X5MM MODIF.	Па
S76019	CESPACE PEEK TRIAL IMPL. 5U4X6MM MODIF.	Па
S76020	CESPACE PEEK TRIAL IMPL. 5U4X7MM MODIF.	Па
S76021	CESPACE PEEK TRIAL IMPL. 5° 14X8MM MODIF.	Па
S76022	CESPACE PEEK TRIAL IMPL. 5U6X4MM MODIF.	Па
S76023	CESPACE PEEK TRIAL IMPL. 5° 16X5MM MODIF.	Па
S76024	CESPACE PEEK TRIAL IMPL. 5U6X6MM MODIF.	Па
S76025	CESPACE PEEK TRIAL IMPL. 5° 16X7MM MODIF.	Па
S76026	CESPACE PEEK TRIAL IMPL. 5° 16X8MM MODIF.	Па
S76027	CESPACE PEEK INSERTION ROD 4-8 MM/FJ415R	Па
SC410R	QUINTEX FIXATION PIN NONSTERILE	Па
SC421R	QUINTEX CALIPER	Па
SC422R	QUINTEX FIXATION PIN INSTRUMENT	Па
SC423R	QUINTEX ADJUSTABLE SINGLE DRILL GUIDE	Па
SC424R	QUINTEX ADJUSTABLE DOUBLE DRILL GUIDE	Па
SC425R	QUINTEX FIXED SINGLE DRILL GUIDE 14MM	Па
SC426R	QUINTEX FIXED DOUBLE DRILL GUIDE 14MM	Па
SC430R	QUINTEX DRILL BIT D2.9MM	Па
SC432R	QUINTEX SCREW DRIVER	Па
SC433R	QUINTEX SCREW REMOVAL TOOL	Па
SC450	QUINTEX INSTRUMENTATION	Па
SJ210R	PROSPACE PEEK INSERTION INSTRUMENT	Па
SJ211R	PRO SPACE PEEK IMPACTOR	Па
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SJ219P	PRO SPACE SPACER PEEK/RADIOLUCENT 9MM	Па
SJ220P	PRO SPACE SPACER PEEK/RADIOLUCENT 10MM	Па
SJ221P	PROSPACE SPACER PEEK/RADIOLUCENT 11MM	Па
SJ222P	PRO SPACE SPACER PEEK/RADIOLUCENT 12MM	Па
SJ223P	PRO SPACE SPACER PEEK/RADIOLUCENT 13MM	Па
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SJ234P	PROSPACE PEEK IMPLANT 0° 7X8X22MM	IIb

<p>Prekladateľská doložka:</p> <p>Preklad som vypracoval ako prekladateľ zapísaný v zozname znalcov, tlmočníkov a prekladateľov, ktorý vedie Ministerstvo spravodlivosti Slovenskej Republiky v odbore: slovenský jazyk, nemecký jazyk a anglický jazyk, evidenčné číslo prekladateľa 971273.</p> <p>Prekladateľský úkon je zapísaný v prekladateľskom denníku pod poradovým číslom <u>2971/2022</u></p> <p>Preklad súhlasí s prekladanou listinou.</p> <p>Vyhlasujem, že som si vedomý následkov vedome nepravdivého prekladu</p>	<p>Translator's clause:</p> <p>I produced the above translation as a translator entered in the Register of Experts, Interpreters, and Translators kept by the Ministry of Justice of the Slovak Republic, field: Slovak language, German language and English language, translator's registration number 971273.</p> <p>This translation is recorded in the translator's diary under no. <u>2971/2022</u></p> <p>The translation corresponds to the document translated.</p> <p>I declare that I am aware of the consequences of a knowingly false translation.</p>
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V Prievidzi dňa 19.12.2022

Done at Prievidza on 19.12.2022



Mgr. Tomáš Dobrotka
Prekladateľ – Translator

