OPTICAL FIBERS ARE OUR PASSION

advanced fiber tools GmbH

more than fiber and optical solutions

NATURE IS OUR INSPIRATION

Without nature many of today's inventions would not be possible. Most of the time, when people were looking for a solution to a problem, they were surprisingly successful.

more than fiber and optical solutions

advanced fiber tools GmbH is a manufacturer of **high quality fiberoptic products** for the medical, industrial and scientific applications.

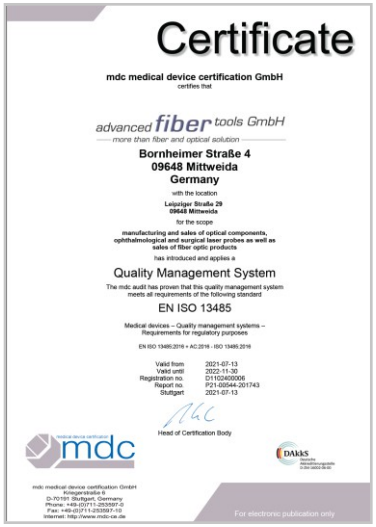
Our technical staff is highly specialized with many years of experience in the fiberoptic sector, concentrating in the medical field.

Our core business is drawing of multimode, single mode, plastic-clad silica, hard polymer-clad silica, high NA and special fibers. Manufacturing of fiber optic devices for the total range of laser surgery, focusing and collimating handpieces are also part of our core business. Industrial cables, bundles, optics (optic calculation) and products for OEM customers complete our products to give a full range of options to our customers.

Board of Directors:
Prof. Dr. G. Kuka (CEO) & Naim Ashraf (General Manager)

QUALITY -
IS OUR FIRST PRIORITY!

With our process and process-oriented
quality management system.



Certificate

mdc medical device certification GmbH
certifies that

advanced fiber tools GmbH
more than fiber and optical solution
Bornheimer Straße 4
09648 Mittweida
Germany

with the location
Leipziger Straße 29
09648 Mittweida

for the scope
manufacturing and sales of optical components, ophthalmological and surgical laser probes as well as sales of fiber optic products

has introduced and applies a
Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard
EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from 2021-07-13
Valid until 2022-11-30
Registration no. D1102400006
Report no. P21-00544-201743
Stuttgart 2021-07-13

Head of Certification Body

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart / Germany
Phone: +49-(0)711-253997-0
Fax: +49-(0)711-253997-10
Internet: http://www.mdc-ce.de

For electronic publication only

EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

advanced fiber tools GmbH
Bornheimer Straße 4
09648 Mittweida
Germany

for the scope
ophthalmological laser probes, surgical laser probes

has introduced and applies a
Quality System

for the manufacture of the products concerned and carries out a final inspection as specified in Annex V, Section 3.

The mdc audit has proven that this quality system meets all requirements according to
Annex V – Section 3
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from 2020-01-23
Valid until 2024-05-26
Registration no. D1102400005
Report no. P19-01139-153680
Stuttgart 2020-01-23

Head of Certification Body

mdc medical device certification GmbH
Kriegerstraße 6
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Phone: +49-(0)711-253997-0
Fax: +49-(0)711-253997-10
Internet: http://www.mdc-ce.de

For electronic publication only

MADE IN GERMANY
advanced fiber tools GmbH
MORE THAN FIBER AND OPTICAL SOLUTIONS

Certified
Quality System
ISO 13485
mdc
CE
0483

The company, advanced fiber tools GmbH, Mittweida, Germany, has a procedure and process-oriented quality management system according to EN ISO 13485 and a quality assurance system according to EC Directive 93/42 / EEC, Appendix V.

The medical devices manufactured and supplied by advanced fiber tools GmbH are subject to the strictest quality assurance criteria.

The medical devices manufactured and supplied by advanced fiber tools GmbH meet the requirements of the DIN EN ISO 10993 ff. in terms of their biocompatibility, depending on the respective purpose.

On customer request, our products can be delivered in a sterile condition. A partner company guarantees a validated ethylene oxide (EtO) sterilisation process according to DIN EN ISO 11135.

The following are available for our devices:

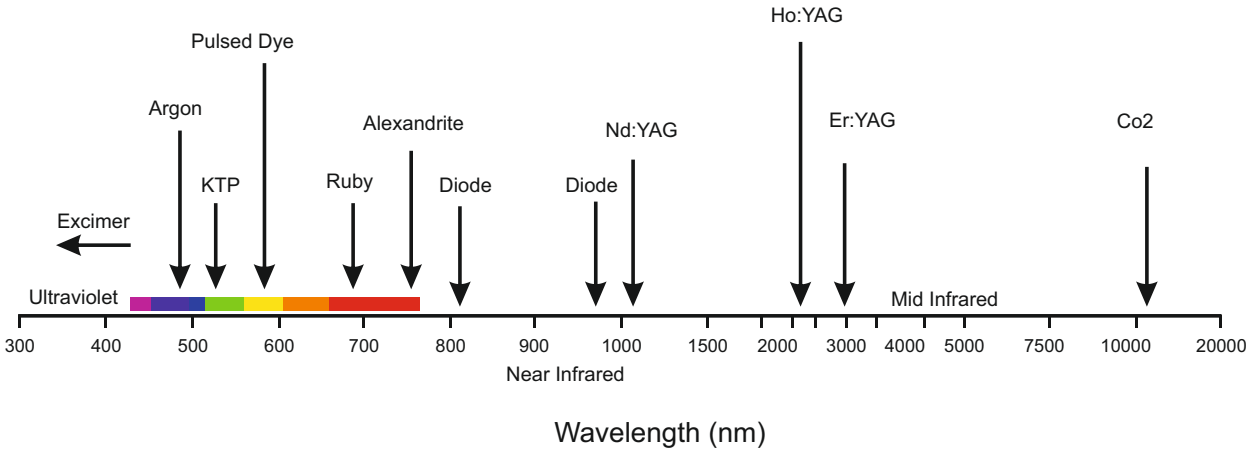
- Sterility certificate according to EN 556-1
- Proof of absence of bacterial endotoxins (LAL-Test according to EP-BE: pH. Eur. 5 Chapter 2.6.14)
- EtO residual gas analysis according DIN EN ISO 10993-7
- Bioburden determination according to EP-ME: pH. Eur. 5 Chapter 2.6.12

MEDICAL APPLICATIONS

- Broncho
- Dentistry
- Dermatologie
- Gastroenterology
- Gynecology
- ENT
- Illumination
- Laser Surgery
- Ophthalmology
- Orthopedics
- Photodynamic therapy
- Urology
- Vein surgery

MEDICAL LASERGUIDE

Medical Laser	Laser Type	Wavelength	Delivery System	Application Range
FAR INFRARED				
Er: YAG	Solid State	2,9 mic	Articulated Arm, Sephire fiber	Surgery, Dermatology, Dental
HO: YAG	Solid State	2,1 mic	Hook Shot Fiber™, Side fiber, Bare fiber	Urology, Surgery, arthroscopy
Co2	Gas	10,6 mic	Articulated Arm, Silver halide fiber, Hollow Waveguide	Surgery, Dermatology
CO2 pulsed / gepulst	Gas	10,6 mic	Articulated Arm, Hollow Waveguide	Surgery, Dermatology, Dental
NEAR INFRARED				
Nd:YAP	Solid State	1080 nm	Bare fiber, opt. Handpieces	Dental
Nd:YAG	Solid State	1064 nm	Bare fiber, Hook Shot Fiber™, Side fiber, opt. Handpieces	Vein treatment, ENT, Dental, Urology, Gynaecology, Gastro, Brocho, PLDD, ITT, LITT, Dermatology
Diode	Semiconductor	810-980 nm	Bare fiber, Hook Shot Fiber™, Side fiber, opt. Handpieces	Vein treatment, ENT, Dental, Urology, Gynaecology, Gastro, Brocho, PLDD, ITT, LITT, Dermatology
Diode	Semiconductor	630-750 nm	Bare fiber, fiber difussor, opt. Handpieces	Vein treatment, ENT, Dental, Urology, Gynaecology, Gastro, Brocho, PLDD, ITT, LITT, Dermatology, PDT
Krypton	Gas-Ion	799.3 nm	Opt. Handpieces	Dermatology
Alexandrit	Solid State	700-800 nm	Opt. Handpieces	Dermatology, Hair removal
Diode	Semiconductor	780-905 nm	Bare fiber, opt. Handpieces	Vein treatment, ENT, Dental, Urology, Gynaecology, Gastro, Brocho, PLDD, ITT, LITT, Dermatology
Krypton	Gas-Ion	752.5 nm	Opt. Handpieces	
VISIBLE				
Ruby	Solid State	694 nm	Opt. Handpieces	Dermatology, Tato removal, Hair removal
Krypton	Gas-Ion	676.4 nm	Opt. Handpieces	Dermatology
HeNe	Gas	633 nm	Bare fiber, fiber bundle, Plastic fiber	Pilot beam
Ruby	Solid State	628 nm	Opt. Handpieces	Dermatology, Hair removal
Frequency dubb. Nd:YAG / KTP	Gas-Ion	350 nm	Opt. Handpieces	Dermatology
Krypton	Gas-Ion	350 nm	Opt. Handpieces	Dermatology
Argon	Gas-Ion	514,5 nm	Endoprobe, Bare fiber, optical Handpieces	Ophthalmology, Dermatology, ENT, Dental
KTP / Frequency dubb. Nd:YAG	Solid State	532 nm	Endoprobe, Bare fiber, optical Handpieces Hook Shot Fiber™, Side fiber	Ophthalmology, Dermatology, ENT, Dental
NEAR ULTRAVIOLET				
Excimer	Gas (excimer)	308 nm (UV-B)	Bare fiber, Multi fiber Catheter	Angioplasty, Dermatology, Ophthalmology
FAR ULTRAVIOLET				
ArF	Gas (excimer)	193 nm (UV-C)	Direct, Sleet Lamp	Ophthalmology


Ho:YAG
Pulsed Dye
Argon
Alexandrite
Nd:YAG
Er:YAG
Co2
KTP
Ruby
Diode
Diode
Excimer
Ultraviolet
Mid Infrared
300
400
500
600
700
800
900
1000
1500
2000
3000
4000
5000
7500
10000
20000
Near Infrared
Wavelength (nm)

MEDICAL DIAMETER CONVERT

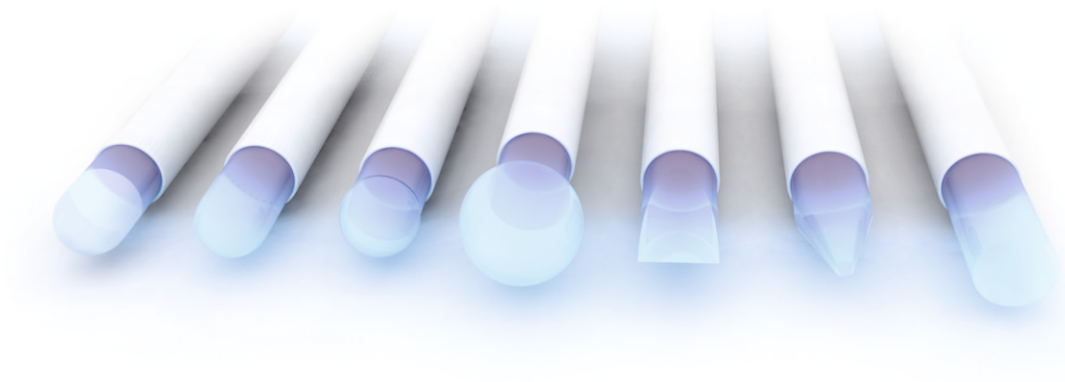
FRENCH (F)

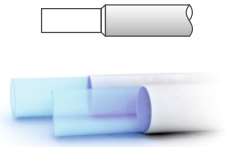
Charrière (CH)	O.D. mm	Charrière (CH)	O.D. mm
1	0.33	24	0.33
2	0.67	25	0.67
3	1.00	26	1.00
4	1.33	27	1.33
5	1.67	28	1.67
6	2.00	29	2.00
7	2.33	30	2.33
8	2.67	31	2.67
9	3.00	32	3.00
10	3.33	33	3.33
11	3.67	34	3.67
12	4.00	35	4.00
13	4.33	36	4.33
14	4.67	37	4.67
15	5.00	38	5.00
16	5.33	39	5.33
17	5.67	40	5.67
18	6.00	41	6.00
19	6.33	42	6.33
20	6.67	43	6.67
21	7.00	44	7.00
22	7.33	45	7.33
23	7.67		

GAUGE (G)

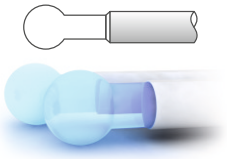
Gauge (G)	O.D. mm	Inches	Gauge (G)	O.D. mm	Inches
35	0.13	0.005	17	1.5	0.059
34	0.18	0.007	16	1.65	0.065
33	0.2	0.008	15	1.83	0.072
32	0.23	0.009	14	2.11	0.083
31	0.25	0.01	13	2.41	0.095
30	0.3	0.012	12	2.77	0.109
29	0.33	0.013	11	3.05	0.12
28	0.36	0.014	10	3.4	0.134
27	0.41	0.016	9	3.76	0.148
26	0.46	0.018	8	4.19	0.165
25	0.51	0.02	7	4.57	0.18
	0.53	0.021	6	5.16	0.203
24	0.56	0.022			
23	0.64	0.025			
22	0.71	0.028			
21	0.81	0.032			
20	0.89	0.035			
	0.97	0.038			
19	1.07	0.042			
18	1.27	0.05			

BARE FIBER

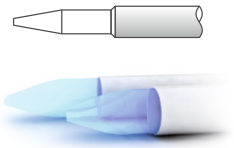




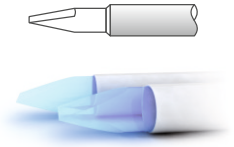
Model	Description	Fiber diameter [µm]
aft BF_400_3_SF	bare fiber 400 mic flat tip	400
aft BF_600_3_SF	bare fiber 600 mic flat tip	600
aft BF_800_3_SF	bare fiber 800 mic flat tip	800
aft BF_1000_3_SF	bare fiber 800 mic flat tip	1000
aft BF_200_3_SB	bare fiber 200 mic ball tip	200
aft BF_400_3_SB	bare fiber 400 mic ball tip	400
aft BF_600_3_SB	bare fiber 600 mic ball tip	600
aft BF_800_3_SB	bare fiber 800 mic ball tip	800
aft BF_1000_3_SB	bare fiber 1000 mic ball tip	1000



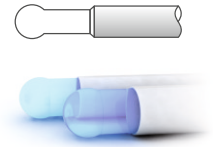
BARE FIBER



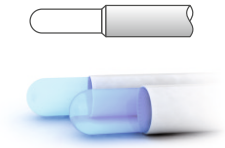
Model	Description	Fiber diameter [µm]
aft BF_200_3_SC	bare fiber 200 mic conical tip	200
aft BF_400_3_SC	bare fiber 400 mic conical tip	400
aft BF_600_3_SC	bare fiber 600 mic conical tip	600
aft BF_800_3_SC	bare fiber 800 mic conical tip	800
aft BF_1000_3_SC	bare fiber 1000 mic conical tip	1000



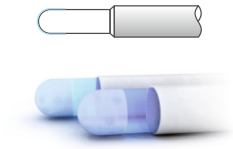
aft BF_200_3_SCH	bare fiber 200 mic chisel tip	200
aft BF_400_3_SCH	bare fiber 400 mic chisel tip	400
aft BF_600_3_SCH	bare fiber 600 mic chisel tip	600
aft BF_800_3_SCH	bare fiber 800 mic chisel tip	800
aft BF_1000_3_SCH	bare fiber 1000 mic chisel tip	1000



aft BF_200_3_SO	bare fiber 200 mic orb tip	200
aft BF_400_3_SO	bare fiber 400 mic orb tip	400
aft BF_600_3_SO	bare fiber 600 mic orb tip	600
aft BF_800_3_SO	bare fiber 800 mic orb tip	800
aft BF_1000_3_SO	bare fiber 1000 mic orb tip	1000



aft BF_200_3_SS	bare fiber 200 mic spherical tip	200
aft BF_400_3_SS	bare fiber 400 mic spherical tip	400
aft BF_600_3_SS	bare fiber 600 mic spherical tip	600
aft BF_800_3_SS	bare fiber 800 mic spherical tip	800
aft BF_1000_3_SS	bare fiber 1000 mic spherical tip	1000



aft BF_200_3_SFR	bare fiber 200 mic frosted tip	200
aft BF_400_3_SFR	bare fiber 400 mic frosted tip	400
aft BF_600_3_SFR	bare fiber 600 mic frosted tip	600
aft BF_800_3_SFR	bare fiber 800 mic frosted tip	800
aft BF_1000_3_SFR	bare fiber 1000 mic frosted tip	1000

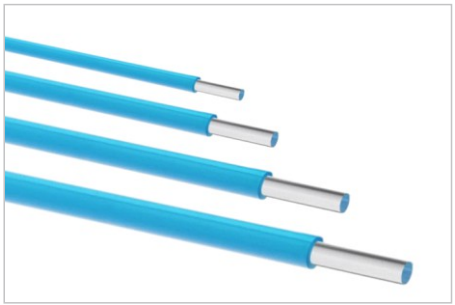
UROLOGICAL LASER PROBES

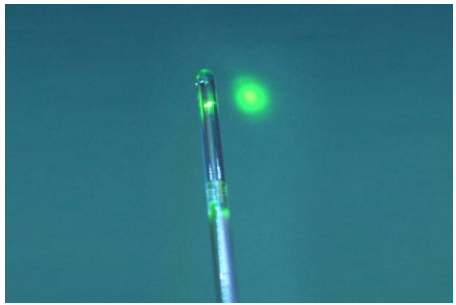
Urological laser probes are used to treat soft tissue and hard tissue urologic conditions.

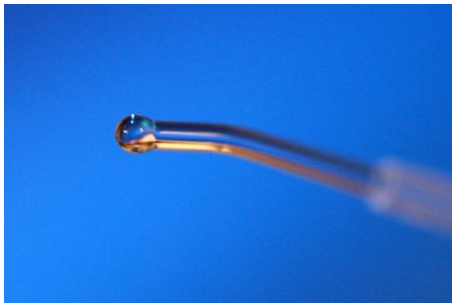
Soft tissue treatment

Many elderly men worldwide are affected by benign prostatic hyperplasia (BPH), which is a benign enlargement of the prostate gland, causing weakening of the urinary stream, frequency, and urgency.

Failure to treat this condition can result in total urinary retention. In addition to drug treatment, minimally invasive surgery with the holmium laser can be used to treat this prostate gland disorder: YAG or diode lasers are used.
For this purpose, various laser probes, such as Side firing fiber, Hook Shot fiber or bare fiber probes are used.







DENTAL LASER PROBES

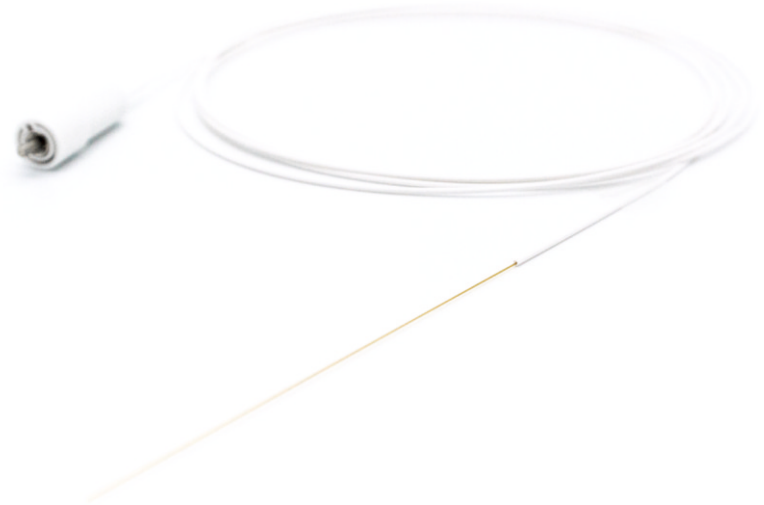
Are used to treat soft tissue and root canal sterilisation.

There are currently two main areas of application for dental lasers. Depending on the laser wavelength and absorption range, the systems can be used to treat soft tissue or hard tissue (enamel, dentine, bone).

For the treatment of soft tissue (surgery, periodontal treatment, etc.), diode lasers with wavelengths of 810 nm, 940 nm, or 980 nm are currently used in combination with dental probes (bare fiber).

Application examples:

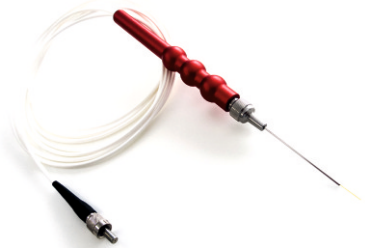
- Periodontal treatment
- Root canal sterilisation
- Minor surgery
- Implantology
- Desensitisation of the dental necks
- Orthodontics
- Implantology
- Endodontics



DENTAL LASER HANDPIECES (APPLICATORS)

Dental laser handpieces (applicators) are medical instruments with mechanical constructions for guiding and fixing the fibers for precise and controlled use, for laser beam interaction on biological tissues and root canal sterilization. These applicators are mostly used in contact mode.

They consist of a **grip** for freehand use, **shaped fiber - guide tubes** and a **fixation unit**. The handpiece is only temporarily connected to the fiber.



BLEACHING HANDPIECES

Bleaching handpieces are medical, fiber-based instruments (beam delivery systems) based on opto-mechanical designs for tooth whitening on a defined tooth surface in non-contact mode.

They consist of a **handle for free-hand use, collimating beam guiding optics and a laser coupling system** (connector)

OPHTHALMIC LASER PROBES

The **ophthalmic laser probes** are medical, fiber-guided instruments (beam delivery systems) with mechanical designs for controlled and precise use in ophthalmology.

The probes are used in combination with laser systems, with a **wavelength of 810 and 532nm** for the treatment of a variety of eye diseases

For this used probe types are:

- bare fibers / shaped fibers
- endoprobes
- cyclo probes
- retino probes
- illumination probes

FOCUSING HANDPIECES

Focusing laser handpieces are medical, fiber-based instruments (beam guidance systems), based on opto-mechanical constructions for the realization of laser beam interaction on biological tissues, on a defined and smallest possible surface in non-contact mode.

They consist of a handle for **free-hand application**, **focusing beam guiding optics, spacers and a laser coupling system** (plug).

COLLIMATING HANDPIECES

Collimating laser handpieces are medical, fiber-based instruments (beam guidance systems) based on opto-mechanical constructions for realizing laser beam interaction on biological tissues on a defined long focal length in non-contact mode.

They consist of a **handle for freehand application**, **focusing beam guiding optics** and a **laser coupling system** (plug).

make your products safer ... with RFID Technology

RFID technology is increasingly finding application in medicine for the identification and identification of medical instruments, medical laser probes and other consumables.

The use of the RFID technology enables a safe and optimized sequence of the process for the patient and the user in comparison to conventional identification technologies such as the barcode in various medical fields.

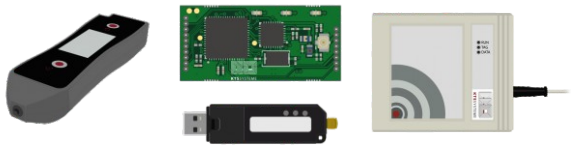
The speed of identification is increased, paper-based processes are eliminated and thus integrated, media-free business processes are made possible.

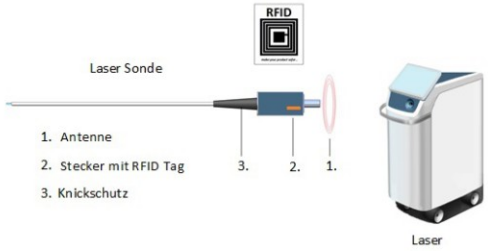
Types of RFID:

- RFID NFC tag / transponder
- RFID NFC tag / labels
- RFID NFC tag / metal nameplates
- RFID NFC tag / cards

Advantages:

- Contactless data exchange
- Store larger volumes of information
- Faster deployment and usage options





CONTRACT MANUFACTURING CHART

advanced fiber tools GmbH — customer

confidential agreement

product, technical file with customer specification

definition of the intended purpose and the essential requirements
according directive 93/42/EWG Annex I

Contract Manufacturing Agreement

production of medical fibers by advanced fiber tools GmbH under following conditions/requests

quality management system according EN ISO 13485

CE-certification according directive 93/42/EWG Annex V

risk management according EN ISO 14971

applied materials according USP class VI, EN ISO 10993 ff

manufacturing in a clean room according class 100.000 (US-Norm Federal Standard 209 E) and class 8 (EN ISO 14644-1) respectively according GMP, Annex 1, class D

packaging medical fibers in sterile bags according EN ISO 11607-2

standard operating procedures for manufacturing, packaging and testing

ETO-sterilization based on a validation report according EN ISO 11135

delivery of medical fibers to customer with following documents for each charge

declaration of conformity according directive 93/42/EWG

sterilization certificate according EN 556-1 optional certificates: endotoxin test (LAL test) according EP-BE: Ph. Eur. 5 Chapter 2.6.14, EO/ECH/EG - sterilization residual analysis according EN ISO 10993-7, BioBurden determination according EP-ME: Ph. Eur. 5 Chapter 2.6.12

headquarter

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Germany

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