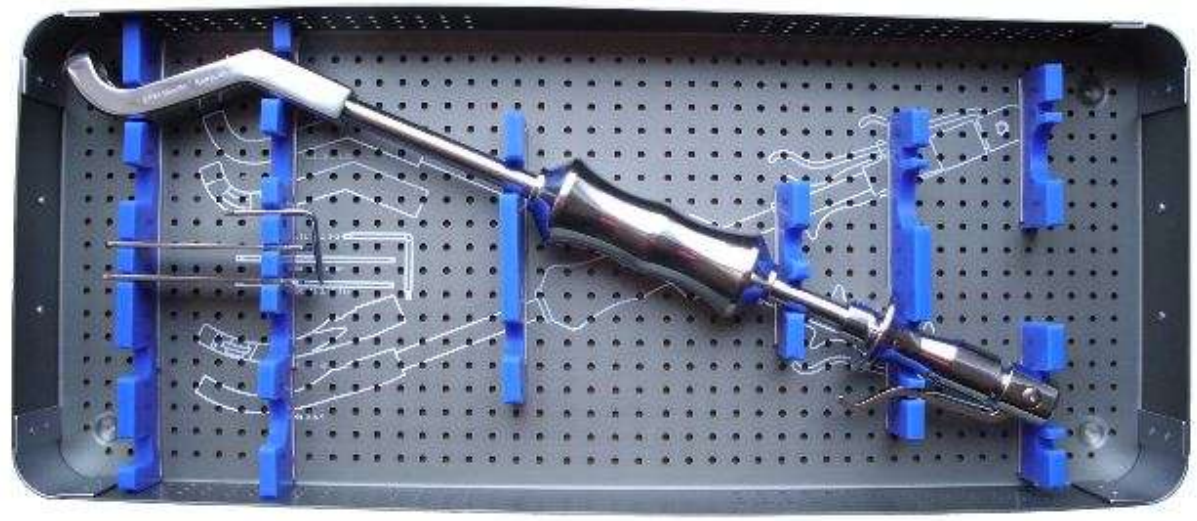
Extraction Tools for Total Hip Replacements
EPM Mueller® Extractor SA
for Anterior Approche Surgery

„Knockout Tool for Joint Prosthesis“
CE, ISO 13485
FDA Establishment Registration Number: 3003759646
Patented in most countries, USA Pat.Nr.5.534.006, USA Pat.Nr. 8.603.100B2,
EP 0.645.127, DE 43.32.872 C1

Technical Documentation



www.epm-mueller.de

Technical Documentation

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Developed by EPM Endo Plant Müller GmbH

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1. Introduction

Since its inception in the early 60's, total hip replacement surgery has become enormously important; today it is one of the most successful surgical interventions in orthopedics.

One of the problems in total hip replacement and joint replacement surgery in general, is the limited survival time of the implants which have not reached the biomechanical qualities of the natural hip joint. Today a survival time of 10 to 15 years is considered normal if no complications occur.

After years of implantation time the devices loosen aseptically. This loosening is induced by wear particles. A loose prosthesis causes pain, which makes a revision operation necessary. (Fig. 1)

One of the problems during Revision Operations is the removal of the femoral component from the femora. Even if the implant is loose and micro motion is possible, they are still fixed by soft tissue and therefore hard to remove.

Fig. 1

Fig. 2

2. Definition of Medical and Technical Purposes

2.1. High, accurately directed forces have to be applied to the femoral component for short periods of time so that the extraction impulse only acts upon the femoral component itself. (Fig. 7)

2.2. The energy of the extraction impulse has to be so high that the connection between implant and femora (i.e. cement femora) is terminated before the energy of the impulse is transferred to the femora. (Fig. 5)

2.3. To achieve this, uniaxial force transfer is necessary as well as an extremely high connection force between instrument and femoral component. (Fig. 4)

2.4. The force vector has to be as close to the longitudinal axis of the femoral component as possible. (Fig. 4)

3. FEM-Analysis of Revision with Conventional Extraction Tools

To visualize the special relationships and magnitudes of force potentials, and to compare the loads acting upon the cortical bone of the femora in revisions of the femoral component, a finite element strain analysis of the femora while extracting a femoral component with different extraction devices was performed.

3.1. Finite-Element-Modeling (FEM), Conditions and Loads:

For the Finite-Element-Analysis (FEA), two identical femora with two identical femoral components were modeled. (Fig. 3,7). The femora were comprised of 3-D elements. The femoral component outside of the bone and heads of the extraction instruments were compiled of 2-D elements. For the calculations, the near-half symmetry of femora and femoral components were used.

At the ends of the heads of the extraction instruments a ramp force profile of F=0 N at time t=0s to F=10 kN at t=30 ms was imprinted in axial direction. The axial direction is parallel to the middle axis of the femora in the FEM. Therefore this represents a best case for the conventional extraction instruments. (Fig. 3)
The femora is imbedded in 2-D elements, which represent the properties of the muscle surrounding the bone. A strain-free condition is assumed at t=0. Fig. 3

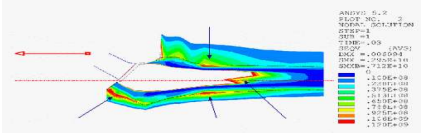


Fig. 3

3.2. Results and Discussion

To depict the strains inside the femurs and femoral components, the von-Mises-strains (s EQV) were used. The FEA was performed in a transient mode. The diagrams 3 and 7 show the von-Mises-strains at maximal extraction forces at t=30 ms.

One can notice the non-homogenous distribution of strains inside the femoral component when conventional extraction tools are used. (Fig. 3). One can deduct an asymmetrical transfer of forces to the femora from this, which can only lead to a partial disconnection of the implant from the surrounding tissue. Therefore, multiple applications of the forces have to be performed.

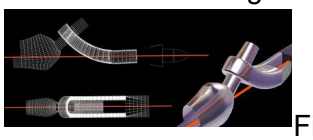
Looking at the distribution of the strains in the cortical bone, extraction with conventional tools causes high strains on the whole (Fig. 3, ABC) and especially high maximal strains in the middle of the prosthesis and at the lower end of the prosthesis. (Fig. 3, D)

With the conventional extraction tools, the force vector is not directed along the longitudinal axis of the femoral component - in the optimal case it is only parallel to this axis (Xp) - the femoral component therefore jams and is hard to remove. The energy impulse is conveyed laterally to the femora.

Fractures of the trochantor or the shaft of the femora can occur. (ABC). A misalignment between extraction vector and the longitudinal axis of the prosthesis can lead to injury of the bone surrounding the prosthesis, to fractures and associated lengthening of the surgical time and anesthesia, increasing of the risk of infection, etc.

4. Principle and Construction of the EPM Mueller® Extractor.

- Provide Axial force transfer and maximal clamping force.
- Ensure the necessary clamping force is transferred to the neck of the prosthesis via a curved toolhead. (Fig. 4).
- The size of the toolhead is minimized because of limited space during surgery.
- The instrument is handled outside of the surgical field.

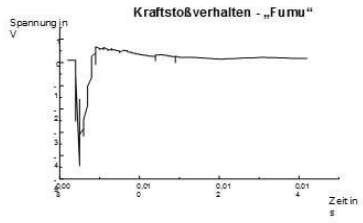


(CAD picture)
Fig.. 4

5. Measurements of Functional Prototype

The prototype was measured with a special trial set-up and a Piezo-force sensor. The profile of force application was registered to monitor change of force over time and calculate the transferred impulse.

A force was applied by hand via a weight against an infinitely hard base and registered by the Piezo-sensor. Data were acquired by an oscilloscope and stored.
The prototype of the extraction instrument is fixed and the weight (800g) is accelerated to about 10m/s.
During the whole time of the experiment, the oscilloscope stores the strain delivered by the Piezo-sensor (strain proportional to force). The impulse transfer time t is calculated from the strain-time-diagram. (Fig. 5).



Results:

From the graph of force transfer time of t=500µs can be derived.
A peak force of 50kN can be calculated for force transfer. Fig. 5
This peak force corresponds to a set-up with an infinitely hard base. In practical use an elastic
fixation exists and consequently the measurements stated above will not be attained.
Duration of the force: 0,5ms (=0,0005s)
Amount of force: 50Ns
The impulse is high enough to overcome the holding forces inside of the bone and loosen the prosthesis.
The clamping mechanism reliably transfers the force to the implant.
Calculated clamping force at the neck of the prosthesis is 30kN.

6. The EPM Mueller® Stem Extractor SA, AU, S, MO

EPM Mueller® Extractor SA with closed head, one slider spacer and one slider bar proper for the Anterior Approche Surgery technique.


Fig. 6a

EPM Mueller® Extractor AU -with open head on the side and one sliding spacer, proper also for stems with fixed heads (monobloks)


Fig. 6b

EPM Mueller® Extractor S -closed head with single sliding spacer


Fig. 6c

EPM Mueller® Extractor AU-S2 with 2 exchangeable heads (open **AU**+ closed **S**) and one sliding spacer


Fig. 6d

EPM Mueller® Extractor MO for modular stems


Fig. 6e

The EPM Mueller® Extractor is characterized by axial force transfer and exceptional clamping mechanism.
The necessary clamping force is transferred to the implant neck by a curved toolhead.
The size of the toolhead is adapted to space restrictions dictated by the surgical procedure.

The EPM Mueller® Extractor is handled outside of the surgical field.
The EPM Mueller® Extractor AW6 has been in clinical use since 1993, the EPM Mueller® Extractor AU since 1999, the EPM Mueller® Extractor S since 2004, the EPM Mueller® Extractor MO and SA since 2014.
The EPM Mueller® Extractor can be fixed to the exposed neck of the prosthesis with a few easy movements and the prosthesis can be removed with limited time and force requirements. The EPM Mueller Extractor can be removed from the prosthesis after extraction via an easy snap-lock mechanism without additional tools. It can be disassembled and assembled easily and fits into a standard surgical tray.
Easy cleaning and sterilization are assured; the instrument is fully autoclavable.

7. FEM-Analysis of Revision with the EPM Mueller® Stem Extractor

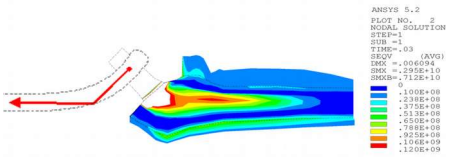


Fig. 7

The direction of force of the EPM Mueller® Extractor (normal case) lies in the middle axis XY of the femora (Fig. 7).
The strain distribution in the prosthesis during extraction with the EPM Mueller Extractor is homogenous, which favors the detachment of the implant from spongiosa and soft tissue.
Strain in the cortical bone is low and shows no peaks.
Therefore the risk of fracture of the cortical bone is minimized.
The EPM Mueller® Extractor is optimized for practical application. The extraction forces are applied to the relevant sides, the clamping force is extremely high and dependable and the device can universally be used for the most implant necks.
Also at the the EPM Mueller® Extractor SA the extraction forces are applied to the relevant sides and the extremely high clamping force leads to a strain and homogenous distribution of the extraction force in the prosthesis.

8. Surgical Use in Garmisch-Partenkirchen-Hospital of the EPM Mueller® Stem Extractor

The EPM Mueller® Extractor has been in clinical use in Garmisch-Partenkirchen-Hospital since October of 1993. At the time of writing, EPM Mueller Extractor has been used during over 600 total hip revision operations in the hospital. A large number of femoral components have been successfully removed; with only a few was extraction not possible. These failures were primarily in the experimental phase, using the prototypes (AW3/4); the geometry of the instrument head has since been changed accordingly.
EPM Mueller® Extractor AU has been in clinical use since 1999.
The remaining failures were due to a maximal stability of the implant in the surrounding bone, meaning an absence of loosening. Stable implants cannot be removed by an extraction tool alone.
To date no complications, for example bone fractures, have been noted.
Handling has proven to be safe and easy. The posture approach usually favored in GarmischPartenkirchen often leads to restricted available space at the operative site; the limited size of the toolhead and the handling of the instrument outside of the surgical field have therefore proven extremely useful.
The surgical personnel have praised easy handling, cleaning and sterilization of the EPM Mueller® Extractor. All parts of the EPM Mueller® Extractor can be assembled and disassembled with ease and safety.
The space needed for storage is minimal and since the instrument can be used universally it is not necessary to maintain a large inventory of extraction devices

9. Use Instructions

EPM Mueller® Stem Extractor SA

Contents:

Fig. 8

9.1. DESCRIPTION

The universal extraction device for total hip replacement femoral components **EPM Mueller® Extractor** is a modern surgical instrument which addresses problems arising through the increasing number of revision surgeries in total joint replacement.
It ensures secure, efficient, low cost and correct handling. Ergonomic aspects concerning the design of the grip and handling have been incorporated into manufacture as a result of ongoing feedback and development.
Key part of the instrument is the patented clamping mechanism and head with exceptional clamping force ensuring a secure connection between the instrument and almost all implant necks or tapers, commercially available today.
The applied force is transferred to the prosthesis' neck axially, thereby avoiding dangerous eccentric leverage.

9.2. COMPONENTS

9.2
EPM Mueller Extractor SA

1 Head of Tool	3 Guiding Tube	6 Handpiece	9 Bolt with plasticinset
2a Sliding Spacer	4 Striking Weight	7 Jamcase	10 Lever
2b Sliding bar	5 Pressure Rod	8 Pin screw	

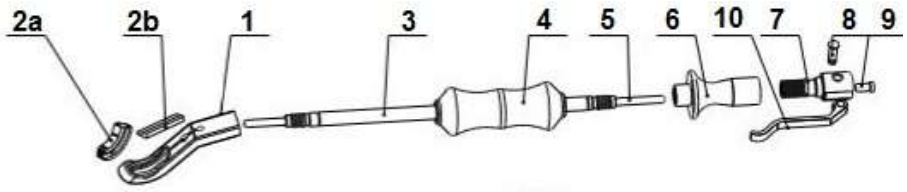


Fig. 9

9.3.1. HANDLING

The EPM Mueller Extractor SA is delivered completely assembled and ready for use.

(**NON STERILE**!) Sterilization is the responsibility of the User.

9.3.1 OPENING

Open lever (**1**) and thread between jamcase and handpiece (working thread) with circular movements reverse clockwise (**2**).
ATTENTION: the threads at the guiding tube have to be always closed complete!

To enable clamping, move the slider spacer and slider bar back by putting pressure on spacer (**3**).

9.3.2 APPLICATION and CLAMPING

Slide (**1**) the opening of the tool head as far as possible over the neck of the prosthesis.
Note:
To use the instrument safely and effectively, the orientation of the prosthesis **has to be** analyzed carefully and the EPM Mueller® Extractor **has to be APPLIED AXIALLY**.
For clamping, rotate(**2**) the opened lever at the distal-end (90° to axis) together with the jamcase clockwise until resistance is felt. Close (**3**) the lever to attain maximal clamping force.
Attention:
Do not use additional instruments with the EPM Mueller Extractor! (as HAMMER)

9.3.3.EXPLANTATION

The weight is placed at the end of the guidance tube closest to the prosthesis, and is then moved forcefully towards the distal end of the tool, impacting on the base of the handpiece.

9.3.4 DETACHMENT

The extracted implant is removed from the tool with the same steps explained under OPENING of the instrument.

9.4. CLEANING and STERILIZATION

The new instrument: has to be cleaned up and disinfected before sterilisation.

DISASSEMBLY

To disassemble look at picture 10

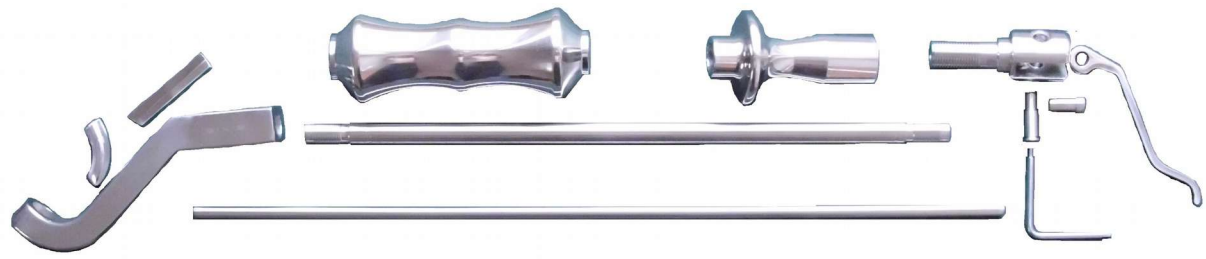
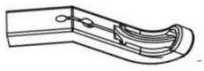


Fig. 10

- 1. Completely unscrew (reverce clockwise) lever assembly (jamcase) of handpiece

- 2. Remove pinscrew, with the 3. Allan key delivered, than pin, than lever, thereafter bolt with plasticinset with a narrow instrument (presure rod can be used
- 3. Extract presure rod
- 4. Detach handpiece by unscrewing completely from the guiding tube
- 5. Slide off the striking weight
- 6. Remove sliding bar through the groove on the front top of the head and then spacer through rectangular space at the instrument head front



- 7. Remove guiding tube by unscrewing completely from the instrument head

Assembly

For Assambly, simply use reverse order.
The EPM Mueller® Extractor is by loosening the screw connections without any additional tools to disassemble, up to the jamcase, which is further disassembled with the supplied 3. Allen key, into single pieces.

ATTENTION: use the bolt always with the plasticinset together!

Preparation

Brand new instruments and those returned from repair must be removed from their transportation packaging before storing and / or inclusion in the instrument usage and processing cycle.

Storage

Store it at room temperature in dry rooms. Condensate may cause subsequent corrosion damage.
Never store it near chemicals such as active chlorine which emit corrosive vapors.
To avoid mechanical damage during processing, store it from the beginning in suitable racks or retainers.

Before using, they must be sent through the entire processing cycle in the same manner as used instruments.

The reprocessing comprises:

- Preparation (pretreatment, collecting, precleaning and taking the instrument apart.
- Cleaning, disinfecting, rinsing, drying
- Visual inspection of clearness and acceptable condition of material
- Care and repair where required
- Functional test
- Marking
- Packaging and sterilization, approval for reuse and storage

Validated cleaning, disinfecting and sterilization processes, supplemented by defined configurations for loading the washers/disinfectors and sterilizers are an indispensable prerequisite for quality assurance.
Automated reprocessing with thermal disinfection and steam sterilization should be preferred.
Use correct water quality!
When using softened water, especially when applying thermal disinfection in the final rinse, anodized aluminium surfaces might be subject to attack due to an increased pH value.

Using demineralised water for steam sterilissation, limit values for feed water quality conforming to EN 285 and ISO 17665 are required.
We recommend using demineralized water for the final rinse for the following reasons:

- No spoting
- No increase in concentration of corrosive constituents, e.g. chlorides
- No dried crystalline residues which could have a negative effect on the downstream sterilization process
- Protection and stabilization of anodized aluminium surfaces

Returned instruments

Only if the instruments have been cleaned, disinfected, dried and have been declarated hygienically safe

Cleaning and Disinfecting

Any residues should be removed.
Never immerse stainless steel instruments in a physiological salt (NaCl) solution, it leads to pitting and stress corrosion cracking.
The passive layer of brand new instruments is necessarily still thin and so these instruments tend to critical treatment conditions than are older used instruments.
Avoid long intervals between use and treatment for reuse.
For manual cleaning, active non-protein-fixing cleaners with or withaut antimicrobial effect and/or enzymes are to be used.
Regarding detergents and desinfectants, the manufacturer`s instruction concerning concentration, temperature and exposure time should always be strictly followed!
Use soft, lint-free cloths or towels, plastic brushes or cleaning guns for cleaning.
To prevent water spots (spotting), a final rinse using fully demineralised water is recommended. After this the instrument must be dried carefully immediately.
By machine-based cleaning, only validated machine cleaning and desinfecting processes (DIN EN ISO 156883 and national guidelines) should be used.

Check and care

Instruments must be checked visually – tactile and be macroscopically clean.
Maintance means targeted application of a lubricant milk to the joints, threads or friction surfaces of instruments. This prevents prevents metal on metal friction and therefore constitutes a preventive measure against friction corrosion.
Requirements for care agents:

- Paraffin/white oil based, in accordance whith the current European or United States Pharmacopeia
- Biocompatible
- Suitable for steam sterilization and vapor permeable

Instruments must not be treated with care agents containing silicone oil.
The proper functioning of the instruments must be assured by testing.

Packaging

International standard EN ISO 11607 1 and 2 apply to packed items requiring sterilization.
It must be possible to mark and identify the package with information such as:

- Sterilisation date
- Packer
- Expiry or “use before” date (if date has been defined)
- Contents

Sterilisation

It is important to use only sterilisation methods and sterilizers that allow validated sterilization processes conform national guidelines.
Sterilisation accesories and packaging materials must be selected in accordance with the items to be sterilised as well as with the sterilisation method used.
Steam sterilization is the method of choice and is performed with saturated steam, usually at 134°C.
Use validated steam sterilization processes in accordance with ISO 17665, EN 554 (or DIN 58946 Part 6 in Germany)

Sterile storing

To guarantee the sterility of instruments until they are used on the patient, germ-tight packaging is absolutely essential.
Further requirements for the protected storage of sterile supplies and the prevention of corrosion damage include a dust-free and dry environment and the prevention of temperature fluctuations.

9.5. CARE INSTRUCTIONS

Apply instrument oil to tube, rod and screws periodically to minimize wear friction.

9.6.TECHNICAL DATA

- Instrument can be used with the following tapers and Konus: Æ 8 – Æ 16,
- Striking weight: 1.0kg (2,2 lb) ; 1,7kg (3,74 lb)
- Total weight: 2,36 kg (5.19 lb) with 1,0kg Striking weight, (AU2 or S2)
- Total length: 580mm (22,9 inches) standard ; 665mm (26,2 inches) long
- Hitting distance: 205mm (8.1 inches) standard; 275mm (8.08 inches) long

9.7. ACCESSORIES

Art No.	Description
1001.16.1.SA	EPM Mueller® Anterior Approche Stem Extractor SA
1001.16.2.1.SA	Head of tool SA
1001.16.2.4	Sliding Spacer SA
1001.16.2.3.SB	Sliding Bar
1001.2.17.ST	Guiding Tube ST
1001.2.17.L	Guiding Tube L
1001.2.15.ST	Pressure Rod ST
1001.2.15.L	Pressure Rod L





1001.2.09.N 1001.2.09.S	Striking Weight N (1kg/2.2 lb) Striking Weight S (1,7kg/3.74 lb)	
1001.2.11.ST1	Handpiece ST1	
1001.2.12.ST2	Jamcase ST2	
1001.2.07	Bolt with plasticinset	
1001.2.13.2	Pin screw	
1001.2.13.A2.5-3	Allan key 2.5-3	
1001.2.14.00	Lever	

9.8. WARANTY, SERVICE:

24 month Exchange guarantee after invoice date.

ATTENCION: not following the use, cleaning and care instructions described,

there are no Warranty any more!

International / European / German Sales,

Hotline, Guarantee, Service:

EPM Endo Plant Müller GmbH

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Fax: +49(0)6022-25419

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10. Declaration of conformity EG/CE

F	Konformitätserklärung	
321	Declaration of Conformity	10001

Wir / We
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EPM Endo Plant Müller GmbH
Schleusen Str.8 , D- 63839 Kleinwallstadt

Erklären in alleinige Verantwortung, dass
Declare on our own responsibility that

Das Medizinprodukt „EPM Mueller® Extractor“ Ausschlagwerkzeug für Hüftgelenkprothesen
The medical device „EPM Mueller® Extractor“ Extraction Tool for HIP Prosthesis

Art.-Nr. 1001.16.SA
Produkt Identifikation UMDNS (15-580) : 5000.E . .
. EPM Mueller® Extractor SA, 1000.1016.2000

Allen Anforderungen der Richtlinie 93/42/EWG entspricht.
Meets all the provisions of the directive 93/42/EEC witch apply to him.

Angewandte harmonisierte Normen:
Applied harmonized standards DIN EN ISO 9001:2000, DIN EN ISO 13485:2003

Andere normative Dokumente: GHTF (SG1) DOC No. N029R11, 02.02.2002
Other normative documents GHTF (SG3) DOC No. N 99.10, 29.06.1999

Angewandte nationale Normen: MPG, MPV
Applied national standards

Konformitätsbewertungverfahren:
Conformity assesment procedure:

Medizinprodukt der Klasse I im Sinne der EG-Richtlinie 93/42/EWG, Anhang IX.
Medical device class I, 93/42/EEC, Annex IX

CE

Kleinwallstadt, den 25.01.2017
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E.J.Müller
Dr.med.,Dr.med.stom.IMFKL.
Geschäftsführer