EC Certificate – Full Quality Assurance System

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

Certificate No. MDD-072

Issued to:	adeor Medical AG Martinshof 5, 83626 Valley Germany
Place of production:	adeor Medical AG Martinshof 5, 83626 Valley Germany
Place of production:	Different manufacturers
Product category:	Surgical power unit
UMDNS / GMDN:	16-868 / 37875, 58029
Product category:	Surgical handpieces
UMDNS:	17-949
Product category:	Burs, microsurgical, single use
UMDNS:	15-883
Product category:	Diamond rotary instruments, single use
UMDNS:	11-237
Product category:	Blades, saw, single use
UMDNS:	13-447
Product category:	Perforator, cranial, automatic, single use
UMDNS:	11-334
Product category:	HF electrosurgical instruments – bipolar forceps
UMDNS:	11-502

SIQ has audited the quality system in accordance with MDD Annex II excluding (4) and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex II. This certificate is based on

Audit report No.:
OSV 01523/2020, 2020-12-29
OSV 00539/2021, 2021-05-11
OSV 00097/2021, 2021-05-19

See also decision of NB`s commission for medical devices.
This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex II (5) and continues to meet the above requirements.

Certification date: 2017-03-31

Issue: 4/2021-05-20

Valid until: 2024-05-26

SIQ Ljubljana
Mašera-Spasićeva ulica 10
1000 Ljubljana

Director of SIQ

adeor medical AG Martinshof 5 83626 Valley Germany

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Regulatory Affairs Manager

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adeor medical AG
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To whom it might concern

21.03.2024

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	adeor medical AG
Manufacturer address and contact details	Martinshof 5 83626 Valley Germany
Single Registration Number (SRN) (if available)	DE-MF-000011451

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Authorised Representative name (if applicable)	n.a.
Authorised Representative address and contact details	n.a.
Single Registration Number (SRN) (if available)	n.a.

Notified body name (if applicable)	SIQ □ See attached schedule
Notified body number (if applicable)	1304 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	MDD-072 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26.05.2024 □ See attached schedule
End date of extended validity/transition period	31.12.2028 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule

or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
☐ A QMS in accordance with Article 10(9) MDR is in place.
☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

adeor medical AG

[redacted]

adeor medical AG
Martinshof 5
D-83626 Valley
Germany

Valley, 21.03.2024

[redacted]

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Meridian Classic and Alpha Perforators	MDD-072	26.05.2024	SIQ Ljubljana	SIQ Ljubljana	31 December 2028	n.a.
HiCUT Instruments	MDD-072	26.05.2024	SIQ Ljubljana	SIQ Ljubljana	31 December 2028	n.a.
Velocity Alpha Highspeed Surgical Drill System	MDD-072	26.05.2024	SIQ Ljubljana	SIQ Ljubljana	31 December 2028	n.a.
Duraguard	MDD-072	26.05.2024	SIQ Ljubljana	SIQ Ljubljana	31 December 2027	n.a.
nxt™ Bipolar Forceps	MDD-072	26.05.2024	SIQ Ljubljana	SIQ Ljubljana	31 December 2028	n.a.

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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Kompatibilitätserklärung / *Declaration of Compatibility*

hiermit erklären wir, die adeor medical AG,
we, adeor medical AG, hereby declare

dass die folgenden von adeor hergestellten Produkte mit dem Medtronic / Midas Rex Legend High Speed Drill System kompatibel sind:
that the following products manufactured by adeor are compatible with the Medtronic / Midas Rex Legend High Speed Drill System:

Produkt Name / *Product name*	UMDNS
HiCUT™ Highspeed Instrumente	15-883
HiCUT™ Highspeed Diamant Instrumente	11-237

In der aktuellen Version der EG – Konformitätserklärung HiCUT Instruments befindet sich eine Tabelle „adeor HiCUT instruments compatible with Midas Rex systems" mit allen von dieser Erklärung betroffenen Artikelnummern.
In the current version of the EC – Declaration of Conformity HiCUT Instruments there is a table "adeor HiCUT instruments compatible with Midas Rex systems" with all article numbers concerned by this declaration.

adeor HiCUT™ Instrumente werden in Übereinstimmung mit dem in Anhang II (vollständiges Qualitätssicherungssystem) beschriebenen Konformitätsbewertungsverfahren unter Ausschluss von Abschnitt 4 der Richtlinie 93I42/EWG (MDD) hergestellt.
adeor HiCUT instruments are subject to conformity assessment procedure described in Annex II (Full quality assurance system), excluding section 4 of the Directive 93/42/EEC (MDD).

[redacted]

adeor medical AG
Martinshof 5
D-83626 Valley
Germany

9.3.2021

Datum
Date