ovesco

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	Ovesco Endoscopy AG
Manufacturer address and contact details	Friedrich-Miescher-Straße 9 72076 Tübingen, Deutschland
Single Registration Number (SRN) (if available)	DE-MF-000006426

Authorised Representative name	Prof. Dr. med. Marc O. Schurr
Authorised Representative address and contact details	Friedrich-Miescher-Straße 9 72076 Tübingen, Deutschland
Single Registration Number (SRN)	DE-MF-000006426

Notified body name	DEKRA Certification GmbH, Stuttgart [X] See attached schedule
Notified body number	0124 [X] See attached schedule
Directive Certificate number to which this confirmation is made	50970-16-05 [X] See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	07.11.2023 [X] See attached schedule
End date of extended validity/transition period	26.05.2024 [X] See attached schedule

[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.

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31-Aug-23

Place of business:
Tübingen, Germany

Company Register:
Stuttgart HRB 727 461

VAT identification number:
DE 217051960

Executive Board:
Prof. Dr. med. Marc O.Schurr,
Chief Executive Officer.
Geoffrey E. Yates,
Executive Board.

Chairman Supervisory Board:
Frank Ramsperger

Bank information:
Baden-Württembergische Bank
SWIFT-BIC: SOLA DEST600
Account 452 030 4
IBAN
DE62 6005 0101 0004 5203 04

Kreissparkasse Tübingen
SWIFT-BIC: SOLADES1TUB
Konto 109949
IBAN
DE43 6415 0020 0000 1099 49

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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:

➢ Expired/expires *after* 20 March 2023:

- 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.

➢ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR is in place.

➢ **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:

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Ovesco Endoscopy AG
Friedrich-Miescher-Straße 9
D-72076 Tübingen
www.ovesco.com

Prof. Dr. med. Marc O. Schurr
Chief Executive Officer
Ovesco Endoscopy AG

[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

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)
AqaNife (200.53.01/200.53.02/200.53.03/200.53.04)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
Argon Precision Cap (200.51)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
AWC (200.57.01/ 200.57.04)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
BARS (component of 100.60)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
BARS Set (100.60)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
BARS Anchor silver (200.12) (component of 100.60)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
BARS Anchor black (200.13) (component of 100.60)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
Coag Dissector (200.50)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	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)

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)
BougieCap 7/8 (400.31.02)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
BougieCap 9/10 (400.31.03)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
BougieCap 11/12 (400.32.01)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
BougieCap 13/14 (400.32.02)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
BougieCap 15/16 (400.32.03)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
BougieCap 17/18 (400.32.04)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
colonic FTRD Set (200.70)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
diagnostic FTRD Set (200.76)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
Fistula Brush PR (200.62)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
Fistula Brush (200.65)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
FTRD Grasper (200.73) (component of article 200.70/ 200.72/ 200.76)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a

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FTRD Marking Probe (component of article 200.70/ 200.72/ 200.76) (component Ref 740059)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
colonic FTRD prOVE Cap (200.71)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
gastroduodenal FTRD prOVE Cap (200.77)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
gastroduodenal FTRD (component of 200.72)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
gastroduodenal FTRD Set (200.72)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
Guide wire (component of article 200.72) (component Ref 740088)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
HemoPill acute (500.01)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
HemoPill monitor (500.05)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
HemoPill receiver (500.20)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
LiftUp (200.56.01)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a

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LiftUp Kit (200.56.02)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
mini OTSC System Set (100.01/ 100.02)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
OTSC Twin Grasper and Anchor OTSC Anchor (200.10/ 200.11/ 200.61) OTSC Twin Grasper (200.44/ 200.45)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
OTSC Proctology (200.60)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
OTSC System Set (100.03/ 100.04/ 100.05/ 100.06/ 100.07/ 100.08/ 100.09/ 100.10/ 100.11/ 100.12/ 100.13/ 100.14/ 100.27/ 200.28/ 100.29/ 100.30/ 100.31)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
OTSG Xcavator (200.15)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a

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remOVE DC Cutter Set 12 (400.02.01)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
remOVE DC Cutter Set 14 (400.02.02)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
remOVE DC Impulse (400.01)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
remOVE Footswitch (accessory 400.06)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
remove FBR set (400.05)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
stentfix OTSC System Set (100.50)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a
Traction Polypectomy Snare (200.55.10)	n/a	07.11.2023	DEKRA	n/a	26.05.2024	n/a