

DEKRA Certification GmbH – Handwerkstraße 15 – D -70565 Stuttgart

Ovesco Endoscopy AG
Herr Chi-Nghia Ho
Friedrich-Miescher-Straße 9
72076 Tübingen
Deutschland

DEKRA Certification GmbH

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Date 2023-10-24

Subject: Notified Body Confirmation Letter

Our reference: 50970-CoL-01, Rev.00

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Mr. Chi-Nghia Ho,

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 on NANDO, hereby confirms that a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer is still pending:

Ovesco Endoscopy AG
Friedrich-Miescher-Straße 9
72076 Tübingen
Deutschland

Furthermore, DEKRA Certification GmbH confirms that an agreement between Ovesco Endoscopy AG and DEKRA Certification GmbH is in place about the surveillance of the products that are covered by the MDD certificate mentioned in table 1 according to Regulation (EU) 2017/745 Article 120.

Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulation (EU) 2017/745 as regards the transitional provision for certain medical devices has been published on 20 March 2023 and came into force on the same day. This Regulation 2023/607 has amended MDR 2017/745 to now identify that under certain conditions certificates issued by Notified Bodies, as DEKRA Certification GmbH, in accordance with the MDD 93/42/EEC that were still valid on 26.05.2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the

certificate, see Table 1 under certain conditions. Additionally, should the Ovesco Endoscopy AG intend to make use of the extension of the validity of the EC-certificates, involvement of DEKRA Certification GmbH for continued surveillance is required.

This Confirmation Letter identifies the products or product groups and EC certificate according to MDD 93/42/EEC (see Table 1) for which Ovesco Endoscopy AG intends to make use of the option for extension of the validity of the EC certificates (see Table 1).

This Confirmation Letter identifies its validity until the latest: **2024-05-25**.

If Ovesco Endoscopy AG has intentions to make use of the option for extension of the validity of the EC certificate (see Table 1) as detailed in the amendment of the MDR 2017/745 by Regulation (EU) 2023/607:

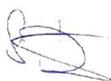
- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

the following conditions have to be met:

- Ovesco Endoscopy AG or its Authorized Representative has to ensure that a formal application acc. to the MDR 2017/745 Section 4.3, first subparagraph of Annex VII for the conformity assessment will have been lodged with DEKRA Certification GmbH, latest by 26 May 2024. The application should be placed for the product(s) or groups of products intended to substitute those product(s).
- Ovesco Endoscopy AG or its Authorized Representative has to ensure that a written agreement in accordance with the MDR 2017/745 Section 4.3, second subparagraph of Annex VII will have been signed with DEKRA Certification GmbH, latest by 26 September 2024.

Should the MDR application not be lodged and the written agreement not to be signed acc. to the mentioned timelines, the EC certificate mentioned in the Table 1, cannot be considered valid after 26. September 2024.

On behalf of the Notified Body,



Digitally signed by Stephanie
Donner
Date: 2023-10-24 13:16:22+02:00

Stephanie Donner
2023-10-24

Enclosures:

Confirmation Letter Annex

Annex to Notified Body Confirmation Letter 50970-CoL-01, Rev.00 dd. 2023-10-24

Table 1: Devices covered by this letter and for which the notified body DEKRA Certification GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Product group identification acc. to MDD -certificate	MDD Device classification	MDD Certificate and Certificate Annex No. with revision
Graspers, applicator caps and brushes used in flexible endoscopy and proctology	Class Is	Certificate acc. to Annex II without Section (4) of MDD 93/42/EEC, registration no. 50970-16-05, valid <i>until 2023-11-07</i> ; with Annex rev. 2 dd. 2021-04-08 NB 0124
Additional working channels for endoscopes	Class IIa	
HemoPill acute	Class IIa	
HemoPill monitor	Class IIa	
LiftUp	Class IIa	
Clipping systems used in flexible endoscopy and proctology	Class IIb	
Endoscopic clipping systems with HF connection	Class IIb	
HF instruments	Class IIb	
DC instruments	Class IIb	
DC generators	Class IIb	