EU Declaration of Conformity (MDR)

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Pursuant to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (MDR).

Parameter	Value
Manufacturer Name / Trademark	eXagotec GmbH
SRN (Single Registration Number)	*DE-MF-000046512*
Authorized Representative (if applicable)	*Not applicable (Manufacturer is based in Germany)*
Manufacturer Address	eXagotec GmbH Reichenbacher Str. 18 97702 Münnerstadt Deutschland (Germany)
Manufacturer's Sole Responsibility	We, eXagotec GmbH, declare under our sole responsibility that the device(s) covered by this Declaration fully complies with the MDR.
Basic UDI-DI *(Annex VI, Part C MDR)*	**426251068HFPH**
Product Name(s), Trade Name(s), Code(s)	1. **HexaFilt** - Product Group: Bacterial and Viral Filter - Article Number: 11000 - UDI-DI (GTIN): 4262510680004 2. **HexaFilt + HexaClip** - Product Group: Bacterial and Viral Filter with Nose Clip - Article Number: 11010 - UDI-DI (GTIN): 4262510680028
Optional: Product Photo	*(Omit or insert images as desired)*
Intended Purpose	HexaFilt (and HexaFilt + HexaClip) is a single-use, non-invasive barrier filter for pulmonary function testing (PFT). It physically filters exhaled breath to reduce cross-contamination in diagnostic equipment (e.g., spirometers).
Risk Class *(per MDR Annex VIII)*	Class I
Compliance with MDR	We declare that the product(s) identified above comply with all relevant provisions of EU Regulation 2017/745 (MDR).
Applied Common Specifications (if any)	No Common Specifications (CS) relevant to this device category have been published by the European Commission. Therefore, no CS apply.
Notified Body & ID (if applicable)	Not applicable (Class I, self-declaration)
Additional Information (if any)	Shelf Life: 4 years; Single-use device; Non-sterile supply
Place & Date of Declaration	Münnerstadt, 2025-02-07
Name & Function of Signatory	Brahim EL ALLAM, PRRC (on behalf of eXagotec GmbH) Alfred Albert, CEO eXagotec GmbH

Declaration Statement

The device(s) covered by this Declaration are medical devices as defined in Article 2(1) of Regulation (EU) 2017/745.

They fulfill the General Safety and Performance Requirements set out in Annex I of the MDR. Conformity has been established via the appropriate conformity assessment procedure for Class I devices. They reflect the current state of the art and comply with all applicable MDR requirements.

The Declaration takes effect on the date of signature.

Place, Date, Name, Role, Signature

Münnerstadt 2024.02.19.

Alfred Albert CEO _____

Brahim EL ALLAM PRRC _____

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