

## Statement

Regulation EU 2017/745 – Article 22

**Nox Medical**

**Katrinartun 2, IS-105 Reykjavik, Iceland**

confirms that the system/procedure packs listed below are put together in compliance with Article 22, “Systems and procedure packs”, of the EU Regulation 2017/745 concerning medical devices.

Systems/procedure packs under scope:

- **Nox RIP Belts and Cannula Kit, s – S/M/L (ATC1SKIT1)**
- **Nox RIP Belts and Cannula Kit, s - M (ATC1SKIT2)**

System/procedure packs Basic UDI

- **1569431111NOX\_ATCKITTM**
- **1569431111NOX\_ATCKITTM**

The mutual compatibility of the devices/products is in accordance with the manufacturer’s instructions and activities have been carried out accordingly.

The system/procedure pack is packed including relevant information necessary for users, incorporating information supplied by manufacturer of the devices or products that are a part of this system/procedure pack as applicable.

The mutual compatibility of the devices/products has been confirmed with appropriate internal monitoring, verification, and validation.

The activities of generating the system/procedure pack are subject to internal procedures at Nox Medical that has a certified Quality Management System according to ISO 13485:2016.



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