nox medical

7 September 2021

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 A1s System with WristOx2, (A1S_EUF)**

System/procedure packs Basic UDI:

- **B-1569431111NOX_A1KITQA**

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.

Kolbrún Eydís Ottósdóttir

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