nox medical

17 March 2017

Statement

- Medical Device Directive 93/42/EEC – Article 12 -

Nox Medical
Katrinartuni 2, IS-105, Reykjavik, Iceland

confirms that the system/procedure packages listed below are put together in compliance with Article 12, "Particular procedure for systems and procedure packs", of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 2007/47/EC.

System/Procedure packages under scope:

- Nox RIP Belts and Cannula Kit – S/M/L (ATC1KIT1)
- Nox RIP Belts and Cannula Kit – M (ATC1KIT2)

The devices/components included in the system/procedure packages are put together within their intended purposes and within the limits of use specified by the manufacturers.

Nox Medical has verified the mutual compatibility of the devices/components in the system/procedure packages.

Nox Medical has packed the system/procedure packages and supplied relevant information to users.

The whole activity of generating the system/procedure packages is subjected to Nox Medical's internal control and inspection system/Quality Management System, certified according to ISO 13485:2016.

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