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 package listed below is 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 package under scope:

- Nox T3 Service Kit (T3_SERVICEKIT)

The devices/components included in the system/procedure package 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 package.

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

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

Kolbrún Ottósdóttir

Kolbrún Eydís Ottósdóttir
Director of Q&R Nox Medical

Nox Medical, Katrinartuni 2, IS-105, Reykjavik, Iceland, +354-570-7170, www.noxmedical.com