AneticAid

Declaration of Conformity to the

Medical Device Directive 93/42 EEC

As amended up to and including the 2007/47/EC amendments

Products covered by this declaration are:

QA3 Patient Trolley System

Catalogue Reference	Description
21110/21112/21114/21116	QA3 Patient/DRIVE/DRIVE Powered/Powered/Patient Trolley
21120/21122/21124	QA3 Emergency/DRIVE/DRIVE Powered/Emergency Trolley

As the Manufacturer, Anetic Aid Ltd. hereby declares that the class I devices specified above conform to the above Directive as transposed in to national regulations and statutes of the United Kingdom, such compliance having been demonstrated via:-

- A Design File compliant to Annex VII
- Compliance to the Essential Requirements as per Annex I
- Internal Quality Assurance procedures to the requirements of BS EN ISO 13485:2016
- Application of the following standards BS EN ISO 14971:2012 and BS EN ISO 13485:2016

The CE marking of product being subject to the maintenance of a registration with the UK Competent Authority, The Medicines and Healthcare products Regulatory Agency based at 10 South Colonnade, Canary Wharf, London, E14 4PU, with reference number CA009086.

The devices are not subject to other directives as defined in article 1 of the Medical Devices Directive 93/42/EEC. The devices do not include animal or human tissue or blood products or derivatives thereof or products that would be considered to be medicinal substances or use Phthalates as defined in the Essential Requirements nor constitute a machine.

This is to certify that the above statement is true and relates to product manufactured from this date.

Signed
For and on Behalf of Anetic Aid Ltd. being a duly authorised officer of the company

Mr Ian Divers
Quality Manager

25th February 2019

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