

Declaration of Conformity

As the manufacturer, Anetic Aid Ltd, 44 New Lane, Havant, Hampshire, PO9 2NF, and having a Single Registration Number of GB-MF-000011932, declares the following medical devices described hereafter:-

QA3 Patient Stretcher System

Have been classified as Class I (Regulation 2017/745, Annex VIII: Rule 1) and are in conformity with Medical Device Regulation 2017/745

Are subject to the procedure set out as follows:-

Annex II & III Medical Device Regulation 2017/745

Please refer to Annex attached listing product part codes applicable under this Declaration.

Competent Authority Medicines and Healthcare products Regulatory Agency (MHRA)
Competent Authority GB/CA 01
Registration No 866

The following Harmonised Standards have been used:-

BS EN ISO 13485:2016
BS EN ISO 14971:2019

The devices are not subject to other directives, do not include animal or human tissue or blood products or derivatives considered to be medicinal substances. The devices do not use phthalates or latex in their construction.

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

Manufacturer

Name: Mr Ian Divers

Position: Quality Manager

Signature: 

Date: 12th October 2021

EU Authorised Representative

EU-UK Authorised Representative Ltd, Unit 591, Moat House, 54 Bloomfield Avenue, Belfast, BT5 5AD, Northern Ireland

Name: Jonathan Phillips

Position: Director

Signature: 

Date: 25th October 2021

Annex

QA3 Patient Stretcher System

Products covered by this declaration are: -

GMDN Code	Catalogue Reference	UDI-DI	Description
33000	21112	05051995000150	QA3 DRIVE Patient Stretcher
33000	21114	05051995000167	QA3 DRIVE Powered Patient Stretcher
33000	21116	05051995000174	QA3 Powered Patient Stretcher
33000	21118	05051995004912	QA3 Ophthalmic Stretcher
33000	21122	05051995000181	QA3 DRIVE Emergency Stretcher
33000	21124	05051995000198	QA3 DRIVE Powered Emergency Stretcher
33000	21126	05051995000204	QA3 Powered Emergency Stretcher
35892	21110	05051995000006	QA3 Patient Stretcher
35892	21120	05051995000013	QA3 Emergency Stretcher