Quality Policy

GBUK Group Limited are committed to designing, manufacturing (through a critical supplier network), and distributing high quality medical devices and the company places a strong emphasis on being able to consistently provide customers with the right products in a cost effective and efficient manner. All employees strive to attain and maintain the highest possible standards of quality and customer service to meet or exceed customer expectations.

To achieve this, we have implemented a Quality Management System which conforms to the requirements of EN ISO 13485:2016, BS EN ISO 14001:2015, European Council Directive 93/42/EEC of June 1993 concerning Medical Devices and the subsequent revisions described in Council Directive 2007/47/EEC, Medical Devices Regulation 2002, Medical Device Regulations (EU MDR) 2017/745 on medical devices, FDA (CFR Title 21 Part 820), The Regulation on In Vitro Diagnostic Medical Devices 2017/746, In-vitro Diagnostic Directive EU 98/79 EC, Rules and Guidance for Pharmaceutical Distributors 2022, as well as local and government legislation, and regulations of all territories in which we operate. We are committed to ensuring that this system remains effective and continuously improves.

To ensure our goals for quality are met, specific Quality objectives are set and monitored by Senior Management during Management Review of the Quality System.

To ensure that this policy is understood throughout the organisation, it is communicated to all our employees during induction and is prominently displayed at key locations in the company. The Quality Policy is reviewed at least annually, at the Quality Management Review, to ensure continued suitability.

Signed:

Mike Geering

Group Chief Executive Officer

Date: Nov 3, 2022

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