

Quality Policy

GBUK Group is fully committed to achieving excellence in all its business operations, focusing on the design, development, manufacture (through a critical supplier network) and distribution of sterile and non-sterile medical devices. The company places a strong emphasis on being able to consistently provide customers with the correct products in a cost effective and efficient manner.

We recognise that the goods and services that we provide serve the needs of patients and Health Care Professionals, worldwide. As such, we are fully committed to maintaining a robust quality system to ensure continued compliance with 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) 2017/45 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 all local government legislation, and regulations of all territories in which we operate to provide confidence that our products are both safe and fit for purpose.

The quality system is continually reviewed to improve its effectiveness.

Our quality objectives are set by the senior management team and reviewed periodically to determine if they remain effective, need amending or if new objectives are required.

To achieve our quality goals, every member of GBUK must be personally committed to, and fully supported in, the pursuit of company quality objectives and a culture of continuous improvement. To this end we are committed to the continual development of our employees.

This policy is communicated to all staff during their induction training and is prominently displayed within GBUK to ensure that it is understood by all.

The quality policy is reviewed periodically by our senior management team to ensure it continues to be suitable to support our business and its goals.

Signed:

Mike Geering

DocuSigned by Mike Geering
 | I approve this document
12-Jun-24 | 11:05:32 AM BST
3915499A2D33431AB9912A355CAFF64B

Group Chief Executive Officer

Date: 12-Jun-24