

Intertek Medical Notified Body AB (the "NB")

Intertek Medical Notified Body UK Ltd (the "UKAB")

Impartiality & freedom from conflicts of interest

It is of the utmost importance that the NB and UKAB provides its services to all interested parties without favor or discrimination, and that its decisions are not capable of being influenced by any commercial, financial or other pressure and are free of any conflict of interest.

This document sets out:

Part A

- How the NB and UKAB safeguards its independence and impartiality
- A guarantee on behalf of the Intertek Group of the NB's and UKAB's impartiality
- Specific measures to avoid conflicts of interest.

Part B

- Declarations of Interest of the NB's and the UKAB's top-level management

Part A

1. How the NB and the UKAB safeguards its independence and impartiality

Although the NB and the UKAB are a legal entities which forms part of the Intertek Group of companies, it is organised and operated so that its independence and impartiality is safeguarded. The relevant organisational, management and independence requirements to achieve this are formally documented in the NB's and the UKAB's Quality Management Manual M001-MED-MDR and M001-1-MED-MDR.

The NB and the UKAB are also participants in Impartiality Committees as part of Intertek's global impartiality procedures (the Impartiality Committee is a "Committee for safeguarding impartiality" in accordance with paragraph 6.2 of ISO/IEC 17021:2011). The function of this Impartiality Committee is to monitor the NB's and the UKAB's impartiality, review any actual or potential risks to such impartiality and address those risks as required.

In addition, all NB and UKAB top-level management, personnel and any sub-contractors commit to adhering to Intertek's Code of Ethics. The "Commitment to Integrity" includes clear rules on prevent conflicts of interest.

2. A guarantee on behalf of the Intertek Group of the NB's and the UKAB's impartiality

The Intertek Group hereby guarantees that it shall not take any action or compel the NB or the UKAB, its top-level management and/or its assessment personnel to take or refrain from taking any action which would jeopardise the impartiality of the services provided by the NB and/or the UKAB.

3. Specific measures to avoid conflicts of interest

The NB and the UKAB takes the following specific measures to avoid actual and potential conflicts of interest.

3.1 No involvement in manufacture

NB/UKAB Personnel are not and are not permitted to be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices within the product category for which the NB/UKAB has been designated, nor the authorised representative of any of those parties. Such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the NB/UKAB and the conduct of the conformity assessment, or the use of such devices for personal purposes.

3.2 No links with manufacturers and being independent of any other economic operator having an interest in the device as well as of any competitors of the manufacturer

NB/UKAB Personnel and top management must be independent of both the manufacturers for whom the NB/UKAB conducts assessments and the commercial competitors (not applicable to UK MDR) of those manufacturers.

In particular, no NB/UKAB Personnel or top management may:

- be or have been directly involved in the design, construction, marketing or maintenance of any devices for which the NB/UKAB is designated.
- engage in any activity that may conflict with their independence or integrity in relation to conformity assessment services for which the NB/UKAB is designated, which the NB/UKAB interprets to include (but does not limit to):
 - holding any employment, consultancy, executive or non-executive position (whether or not remunerated) with any such manufacturer or commercial competitor;
 - holding any ownership, control or voting rights in any such manufacturer or commercial competitor.
 - Holding shares in a manufacturer or commercial competitor for which they take decisions or is involved in any conformity assessment activities for.

3.3 No current consultancy or conflicting services

No NB/UKAB Personnel or top management may offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity, including (but not limited to) offering consultancy services or being linked to any organisation which provides consultancy services which in any way relate to manufacturers devices or processes assessed by the NB/UKAB.

3.4 Disclosure and ring-fencing of prior consultancy or employment conflicts

Any NB/UKAB Personnel or top management who were involved in the field of devices prior to taking up employment with the NB/UKAB are required to fully document that at the time of their employment, and any potential conflicts of interest arising from that are monitored and resolved by the NB/UKAB. Any NB/UKAB personnel who were formerly employed by, or who provided consultancy services in the field of devices to, a client of the NB/UKAB must not carry out conformity assessment activities for that client or any client group company for a period of three years.

3.5 No conflicts of remuneration policy

One important way in which the NB/UKAB guarantees its impartiality is to ensure that the level of remuneration of NB/UKAB Personnel and subcontractors involved in assessment activities does not depend on the results of the assessments.

Accordingly, NB/UKAB Personnel receive a base salary for the work they do. This does not in any way depend on the amount or the result of the number of assessments or certificates that are performed or issued. Performance related/retention bonuses can be paid but (1) this does not apply to any person who is involved in any certification activity or decision; and (2) this would be in line with the Intertek Group's remuneration policies and would be based on overall Intertek Group performance metrics.

PART B

Declarations of Interest

Each member of the NB's and UKAB's top-level management is required to make a declaration of interest. For this purpose, a conflict of interest includes:

- any issue which is deemed to be an actual or potential conflict of interest under Regulation (EU) 2017/45 (MDR) or the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended)
- any issue which is described as an actual or potential conflict of interest under section 3 of Part A above
- any other issue which would conflict with their integrity or independence in carrying out their NB/UKAB responsibilities

These declarations of interest are set out below.

Name	Role	Interest Declared
Curtis Riley	Head of Intertek Medical Notified Body AB (NB 2862)	• Nil return (no conflicting interest)
Brian Mather	Certification Manager	• Nil return (no conflicting interest)
Adrian Yates	Quality & Competency Manager	• Nil return (no conflicting interest)
Sharmila Gardner	Technical Documentation Manager Head of the UK Approved Body (IMNB UK Ltd)	• Nil return (no conflicting interest)
Dawn Chivers	Audit Operations Team Leader	• Nil return (no conflicting interest)
Charlotte Jensen	Planning Manager	Nil return (no conflicting interest)

In addition, although not part of the NB's or the UKAB's top-level management, Director Northern Europe has provided declarations of interest as follows:

Name	Role	Interest Declared
Stefan Eriksson	Country Managing Director Northern Europe	• Nil return (no conflicting interest)

In addition, although they are not part of the NB's or the UKAB's top-level management, the Intertek Group's senior executives of the legal and operating units of which the NB/UKAB forms part have provided declarations of interest as follows:

Name	Role	Interest Declared
Ross McCluskey	EVP EMEA & GTS	• Nil return (no conflicting interest)
Calin Moldovean	President Business Assurance	• Nil return (no conflicting interest)

Timo Lieber	Regional Director ECA Electrical, TT, CW & NTA	• Nil return (no conflicting interest)
Olof Ferenius	GM- Electrical & TT, Sweden	• Nil return (no conflicting interest)
Mark Thomas	Executive Vice President - Assurance	• Nil return (no conflicting interest)