BSI November 2025 Medical Devices & IVDs Capacity and lead times

Applications and conformity assessments

Your partner in progress

Disclaimer

Lead Times indicates the estimated time between the submission of the technical documentation and the point at which BSI is expected to begin its review. It reflects the current scheduled work and the capacity of BSI to initiate work.

The information presented below is based on BSI's interpretation of these terms, considering our operational processes and client feedback relating to information that would be the most useful in enhancing transparency and predictability of MDR/IVDR/UKCA applications, and certification processes for manufacturers.

Capacity and lead times can change rapidly, and they are influenced by several factors. Some of these factors are outside of BSI control such as delays in agreed-upon submissions from manufacturers, change of plans, application withdrawals, last minute cancellations etc. Lead times serve as a reliable indicator of capacity as they are interrelated.

BSI commits to updating the capacity and lead times on a regular basis, and the capacity and lead times presented below should be considered as indicative at the time of publication.

Note: the capacity and lead times figures apply to Approved Body work as well for equivalent device types.

Notified Body and UK Approved Body lead times

BSI is a full scope Notified Body and UK Approved Body and can accept and certify all types of medical devices and in-vitro diagnostic medical devices (IVDs).

Last update: November 2025

Type of application	Capacity	Change as of previous update
MDR Applications (initial, changes etc.)	No restrictions Accepting applications for all device types	No change
IVDR Applications (initial, changes etc.)	No restrictions Accepting applications for all device types	No change
UKCA Applications (initial, changes etc.)	No restrictions Accepting applications for all device types	No change

Notified Body and UK Approved Body lead times

Quality Management System (QMS) audits and microbiology audits

Lead times for Quality Management System (QMS) audits and microbiology audits (for sterile devices) are measured as the earliest time BSI can conduct the QMS and Microbiology audits after the written agreement is concluded between the Manufacturer and NB/UKAB.

Last update: November 2025

Audit type	Device codes	Lead time	Change as of previous update
QMS Audit	All MDT, IVT codes	≤ 2 months	Minus 1 month
Microbiology Audit	For devices associated with sterility, disinfection, cleaning etc.	< 3 months	No change

Technical Documentation assessments

Lead time for Technical Documentation assessments is measured as the average time BSI is able to start the review once complete technical documentation is submitted to BSI.

Last update: November 2025

Technology Team	Type of devices	Device codes	Lead time	Change as of previous update
Active Devices	All active devices except stand-alone software medical devices (as shown below)	MDA 0201 – MDA 0204, MDA 0301 – MDA 0314, MDA 0316 – MDA 0318, MDS 1004, MDS 1009 – MDS 1012, MDS 1014	5 months	No change
Active Implantable Medical Devices	All types of AIMDs	MDA 0101 – MDA 0104, MDS 1009	4 months	Plus 2 months
SaMD	Software as a Medical Device (SaMD) with or without Artificial Intelligence (AI)	MDA 0315	4 months	No change
General Devices	Contraceptives	MDN 1210	2 months	Minus 1 month
	Dialysis and other administration, channeling devices	MDN 1202	2 months	No change
	Soft tissue implants	MDN 1104, MDS 1012	2 months	No change
	Instruments	MDN 1208	2 months	No change
	Ophthalmic	MDN 1206	2 months	Plus 1 month
	Wound care	MDN 1204	2 months	No change
	Anaesthesia, emergency, intensive care, and others	MDN 1201, MDN 1207, MDN 1211, MDN 1213, MDN 1214, MDS 1006, MDS 1010 – MDS 1012	2 months	No change

Last update: November 2025

Technology Team	Type of devices	Device codes	Lead time	Change as of previous update
In Vitro Diagnostic	All types of IVDs	All IVDR codes	> 6 months	No change
Medicinal and Biologics	Devices for IVF/ART, Processing and preserving human organ devices	MDN 1212	3 months	Plus 2 months
	Devices containing an ancillary medicinal substance or ancillary human blood derivative	MDS 1001	3 months	Plus 1 month
	Devices utilizing biological substances such as human tissue derivatives	MDS 1002	4 months	No change
	Devices utilizing biological substances such animal tissue derivatives	MDS 1003	3 months	No change
	Substance based devices to be introduced into the human body via a body orifice or the dermal route	MDN 1213	3 months	Plus 2 months
	Article 117 NB Opinion	Single integral devices to administer a medicinal product	3 months	Plus 2 months
Microbiology	Sterility aspects of devices, sterilants, disinfectants	MDN 1211, MDS 1005, MDS 1006, MDS 1011	3 months	No change
Orthopaedic and Dental Devices	Orthopaedic devices	MDN 1102, MDN 1205, MDN 1208, MDS 1006, MDS 1007, MDS 1013	1 month	No change
	Dental devices	MDN 1103, MDN 1209, MDS 1006, MDS 1007	1 month	No change
Vascular Devices	All types of vascular devices	MDN 1101, MDN 1203, MDN 1207, MDS 1013	2 months	Plus 1 month