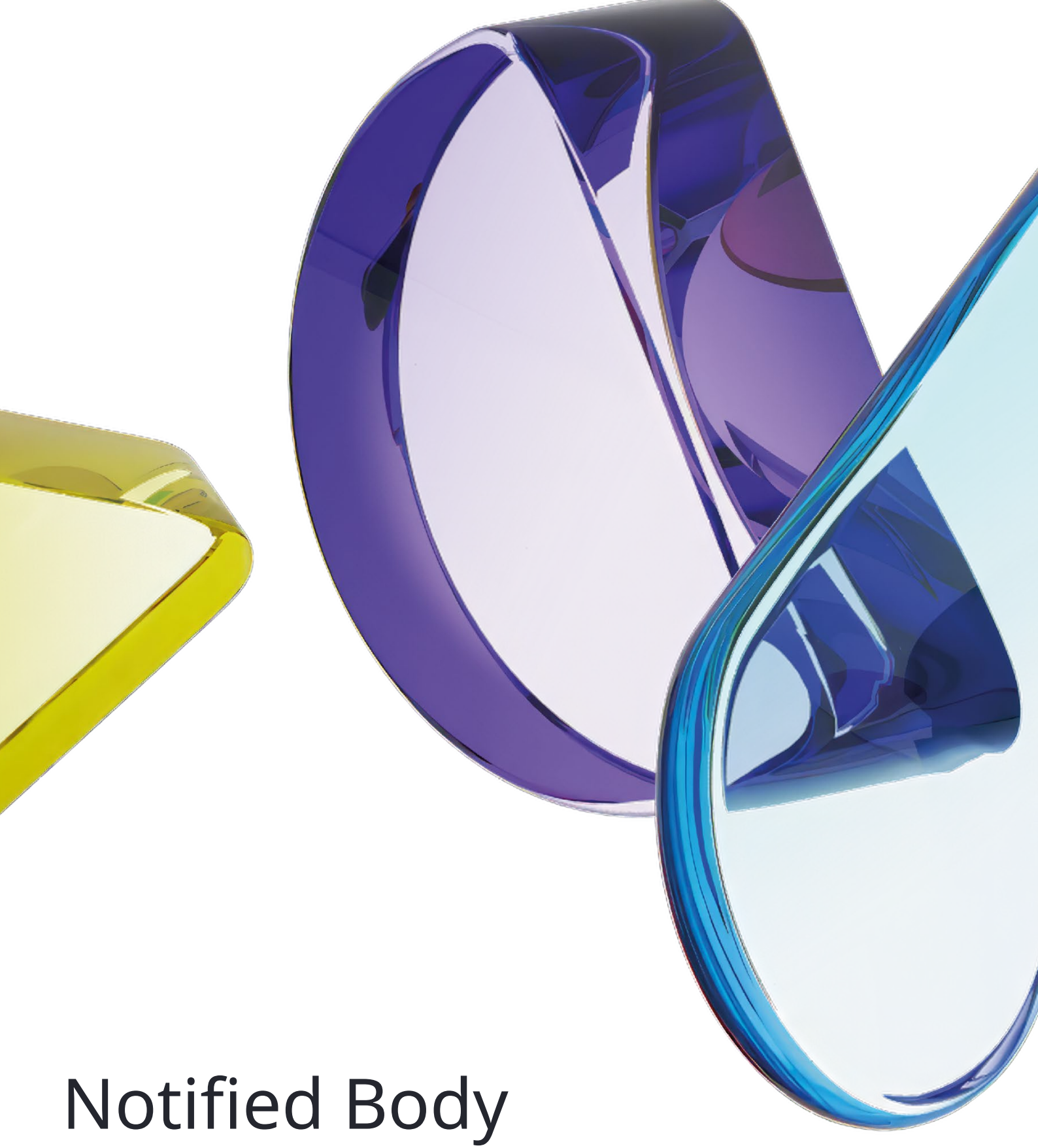

Notified Body capacity and lead times

MDR & IVDR applications and conformity assessments

bsi

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Disclaimer

There are no agreed definitions or specified parameters at EU level for Notified Body capacity or lead times. 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 applications, and certification processes for manufacturers.

Notified Body 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.

Notified Body capacity

BSI is a full scope Notified Body and can accept and certify all types of medical devices and in-vitro diagnostic medical devices (IVDs), as specified in **(EU) 2017/2185**.

Last update: May 2024

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

Notified 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 Notified Body.

Last update: May 2024

Audit type	Device codes	Lead time	Change as of previous update
QMS Audit	All MDT, IVT codes	≥ 3 months	N/A (initial publication)
Microbiology Audit	For devices associated with sterility, disinfection, cleaning etc.	< 2 months	N/A (initial publication)

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: May 2024

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	6 months	N/A (initial publication)
Active Implantable Medical Devices	All types of AIMDs	MDA 0101 – MDA 0104, MDS 1009	< 1 month	N/A (initial publication)
SaMD	Software as a Medical Device (SaMD) with or without Artificial Intelligence (AI)	MDA 0315	2 months	N/A (initial publication)
General Devices	Contraceptives	MDN 1210	1 month	N/A (initial publication)
	Dialysis and other administration, channelling devices	MDN 1202	1 month	N/A (initial publication)
	Soft tissue implants	MDN 1104, MDS 1012	1 month	N/A (initial publication)
	Instruments	MDN 1208	1 month	N/A (initial publication)
	Ophthalmic	MDN 1206	1 month	N/A (initial publication)
	Wound care	MDN 1204	1 month	N/A (initial publication)
	Anaesthesia, emergency, intensive care, and others	MDN 1201, MDN 1207, MDN 1211, MDN 1213, MDN 1214, MDS 1006, MDS 1010 – MDS 1012	1 month	N/A (initial publication)

Last update: May 2024

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	N/A (initial publication)
Medicinal and Biologics	Devices for IVF/ART, Processing and preserving human organ devices	MDN 1212	< 1 month	N/A (initial publication)
	Devices containing an ancillary medicinal substance or ancillary human blood derivative	MDS 1001	< 1 month	N/A (initial publication)
	Devices utilising biological substances such as animal and human tissue derivatives	MDS 1002 MDS 1003	< 1 month	N/A (initial publication)
	Substance based devices to be introduced into the human body via a body orifice or the dermal route	MDN 1213	< 1 month	N/A (initial publication)
	Article 117 NB Opinion	Single integral devices to administer a medicinal product	3 months	N/A (initial publication)
Microbiology	Sterility aspects of devices, sterilants, disinfectants	MDN 1211, MDS 1005, MDS 1006, MDS 1011	3 months	N/A (initial publication)
Orthopaedic and Dental Devices	Orthopaedic devices	MDN 1102, MDN 1205, MDN 1208, MDS 1006, MDS 1007, MDS 1013	6 months	N/A (initial publication)
	Dental devices	MDN 1103, MDN 1209, MDS 1006, MDS 1007	5 months	N/A (initial publication)
Vascular Devices	All types of vascular devices	MDN 1101, MDN 1203, MDN 1207, MDS 1013	1 month	N/A (initial publication)