Your partner
in progress

Subcontractors and Suppliers

Common questions and answers from orthopaedic and dental manufacturers

Contents

During the application for, and surveillance of, CE or UKCA certification, BSI asks for up-to-date information about the critical subcontractors and crucial suppliers associated with devices. Here are some of the most common questions that the Orthopaedic and Dental team receives, with answers.

The approach below is specifically in relation to the MDR 2017/745 (EU) using the same approach applied for the MDD (93/42/EEC, and by inference, UK MDR). This Q&A has been written with a focus from the experience of the BSI Orthopaedic & Dental Team.

Critical subcontractors and crucial suppliers

Why do you need a list of critical subcontractors and crucial suppliers?

Manufacturing processes of devices are critical in the conformity assessment of both the QMS (MDR Annex IX Chapter I & III) and Technical Documentation (MDR Annex IX Chapter II), with manufacture also being referenced in numerous General Safety and Performance Requirements (GSPRs of MDR Annex I), for example:

- **GSPR 1:** "…manufactured in such a way that…they are suitable for their intended purpose."
- **GSPR 4:** "Risk control measures adopted by manufacturers for the…manufacture of the devices shall conform to safety principles…"
- **GSPR 10.2**: "Devices shall be…manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients…"

With regards to assessment of the QMS, Annex IX, Chapter I, Paragraph 3.3 states "audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors."

Regarding the assessment of the Technical Documentation, Annex II, Paragraph 3c states that the technical documentation shall include "identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed."

BSI requires a clear understanding of the suppliers of raw materials, components, and subcontractors performing all manufacturing activities, to inform our approach to planning and conducting audits. We also require clear information and up to date information to determine our plans for unannounced audits. Unannounced audits as part of the Notified Body's surveillance activities were originally required by Commission Recommendation 2013/473/EU, in response to the PIP Breast Implant scandal, and the requirements for unannounced audits are now embedded in the MDR 2017/745 (EU). To allow the Notified Body to determine a plan of which sites to audit, we require manufacturers to provide and keep up to date records of critical subcontractors and crucial suppliers (also differentiating which devices are processed at each site). From this list, we can select, using a risk-based approach, which sites will be best to witness manufacture of devices, and when to audit (avoiding issues such as national holidays or planned site shutdowns).

What are “critical subcontractors” and “crucial suppliers”?

The exact terminology used differs slightly across Commission Recommendation 2013/473/EU, MDR 2017/745 (EU), and guidance document NBOG 2010-1. BSI uses the following definitions (based on those documents) and on the established risk-based approach documented within BSI processes. We communicate these to clients during application and when updating the information.

A “critical subcontractor” is an organization that performs an outsourced process on the manufacturer’s behalf and where the activity or service is critical to the performance and safety of the device(s).

A “crucial supplier” is an organization that supplies a key raw material, or component, the failure of which to meet specified requirements could cause a significant degradation in the safety and performance of the device(s).

Which companies are typically “critical subcontractors”?

Any company, which is not the legal manufacturer (including other companies in the same corporate group), performing a manufacturing process that could impact the safety or performance of the device. Manufacturing activities that are critical include:

- processing of polymers that is critical to performance (e.g., crosslinking, annealing, Vitamin E infusion);
- additive manufacture;
- ceramic casting and sintering;
- coating processes (e.g., Titanium Nitride, plasma sprayed Titanium, Hydroxyapatite);
- final cleaning;
- packaging for terminally sterilised devices;
- packaging for devices that are placed on the market clean, sealed, and not intended to be cleaned & sterilised by the end user;
- sterilisation (all modes);
- final release;
- and critical process which requires specific process validation, and outcome of process compliance cannot be monitored through verification activities.

Virtual manufacturers

Note that if manufacture is fully subcontracted, (i.e. the legal manufacturer is a “virtual manufacturer”), the company or companies performing manufacture would be considered critical subcontractors. Examples include:

- a company providing suture material, cut to the desired length, for later assembly with the device as a whole;
- a company providing a finished knee implant (even if packaged by the legal manufacturer);
- a hip implant manufactured by subcontractor A, and packaged by subcontractor C.

Control of subcontractors

If the legal manufacturer cannot demonstrate sufficient control over the output from a critical subcontractor (e.g., a suitable level of inspection by a subcontractor), the need for audits at the subcontractor would be considered.

Beyond manufacturing

Whilst this Q&A is focused on manufacture, the subcontracting of key quality system activities such as design, development, regulatory compliance, and complaints handling is also critical. This applies even when subcontracted to a different site within the same corporate group.

Are there borderline cases for “critical subcontractors”?

Yes. There are a range of manufacturing activities that are often critical, but risks can be mitigated by appropriate quality controls. Examples are provided below, but please note that these are evaluated on a case-by-case basis (in line with our risk-based approach) as it is highly dependent on the device, manufacturing activity, and quality system controls in place.

Note that the approaches described below can only be used with regards to processes for which the output can be fully verified through inspection of manufactured devices.

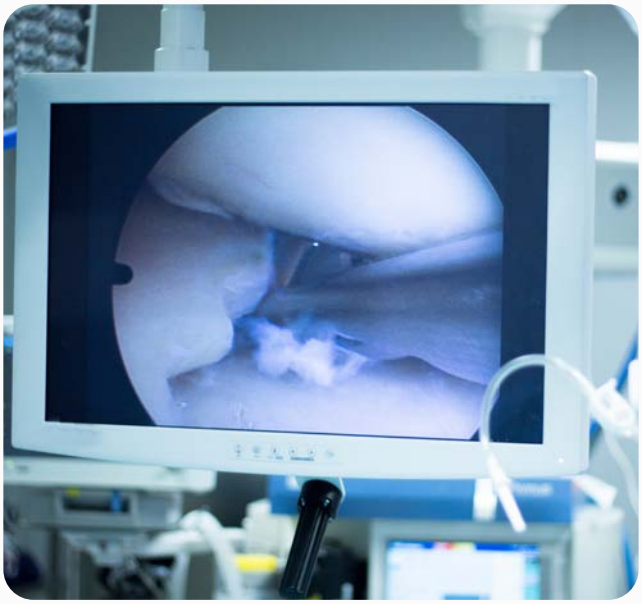
Subtractive manufacture

Subtractive manufacturing processes are often used to create finished dimensions of devices. Where those dimensions are critical to performance or safety (e.g., grinding the bearing profile of a femoral component of a knee arthroplasty, machining the connection dimensions of a dental implant), the subcontractor is critical.

However, it is often the case that further inspections are performed. Where the legal manufacturer, or a later subcontractor holding appropriate certification (explained in question 6), performs sufficient inspection of the critical dimensions, the machining subcontractor can be reclassified as a “crucial supplier”. The requirement for inspection in this scenario is typically to sample every item in a batch, but approaches using process capability data can be considered, and this is considered on a case-by-case basis. Note that if a later subcontractor performs the inspection, that subcontractor would be critical.

Laser marking or engraving

Laser marking or engraving traceability or identification information is critical. However, as with machining, BSI can consider which site performs further inspections.



Surface finishes

The criticality of surface finishing depends on the impact on device function. Finishes that have aesthetic purposes only would not be considered critical. A classic example of a critical surface finishing operation is the polishing of bearing surfaces.

As with the above examples, BSI can consider which site performs further inspections, though the inspection method must be appropriate for the surface finish specification.

Welding

The criticality of welding depends on factors such as the intended use of the device, the function of the weld itself, and the severity of harms associated with the failure of the weld. For example, a structural weld in an implantable component would be critical.

Aspects of the process can also be considered – for example laser welding is often computer numerically controlled, whereas TIG welding is commonly a manual process. Non-destructive inspections of a weld, such as eddy current or ultrasonic inspection, can be considered.

Finally, certification of the subcontractors’ staff (e.g., ISO 9606-1 “coded welders”) can be considered.

Which companies are typically "crucial suppliers"?

Crucial suppliers most commonly provide higher risk raw materials, such as:

- **medicinal substances** – due to the potentially significant patient harm associated with failure to meet pharmacological specifications.
- **human or biologic materials** – due to the potentially significant patient or user harm associated with transmissible agents and need to ensure the requirements of Directive 2004/23/EC and Directive 2002/98/EC have been met.
- **animal tissues** (that are present in the finished device) – due to the potentially significant patient or user harm associated with transmissible agents, and need to ensure the requirements of Regulation (EU) 722/2012 have been met.

Further suppliers are considered on a case-by-case basis by the Scheme Manager based on criticality, controls in place and safety concerns. Examples include:

- **castings** – due to the importance of the process to a component's mechanical properties.
- **forgings** – as with castings.
- **raw materials not produced to an established standard/specification** – these potentially carry additional risk compared to standard raw materials.

Are there any additional requirements for critical subcontractors or crucial suppliers?

In line with our risk-based approach, BSI requires critical subcontractors to hold valid ISO 13485 or MDSAP certification, with a scope appropriate for the activities being performed, at the site performing them. It must also be issued by an EU Notified Body (for MDD or MDR) or UK Approved Body (for UK MDR). The issuing entity can be within the same corporate structure as the EU NB or UKAB (for example, BSI Americas is related to BSI Group the Netherlands B.V. 2797). The reason for this requirement is that it demonstrates the issuing entity has competence in relation to the EU or UK Medical Device Regulation, and BSI can fully rely on the certificate issued. This is the risk-based approach that BSI has implemented based on the Commission Recommendation 2013/473/, and guidance MEDDEV 2.5/3 Rev 2.

The approach has been accepted by our Competent Authorities during designation audits.

High risk crucial suppliers, such as those supplying medicinal substances or animal tissues, must hold a certification appropriate to the industry and item being supplied (this may not be ISO 13485) – for example for medicinal substances, a GMP certificate issued by an EU Medicines Agency or Competent Authority.

BSI does not require other crucial suppliers to hold any certification, but we will ask during the application, assessment and certification processes whether these sites hold any certification, to consider the overall risk presented by the site.

Critical subcontractors: They hold ISO 13485, but it is not issued by an EU Notified Body designated for MDR or UKAB designated under the UK MDR. What happens next?

In line with our risk-based approach, the following situations prompt BSI to consider if additional audits are required:

- a critical subcontractor does not hold ISO 13485 certification.
- a critical subcontractor's ISO 13485 certification was not issued by an EU Notified Body for medical devices (in relation to an EU MDR application), or a UKAB (in relation to a UK MDR application).
- a critical subcontractor's ISO 13485 certificate scope does not cover the activities performed.

If additional audits are required, this is typically a 1-day verification visit audit type initially, then every 2 years, at the subcontractor location. The frequency and duration of the audit can vary depending on the size of the subcontractor and nature of the activities. The criterion for these audits is the contract (supplier quality agreement) with the legal manufacturer, and the requirements of ISO 13485 and relevant legislation (EU MDR, MDD or UK MDR).

We can take other factors into account, such as the level of risk posed by the activity performed by that subcontractor, the level of control applied by the legal manufacturer, or whether the subcontracted process is appropriately validated. This is part of BSI internal risk-based approach process, as described in questions one and two. Examples are included in question 4 above.

Subcontractor and supplier information

When manufacturing is subcontracted to a company, a variety of second or even third tier subcontractors may be involved. Is it necessary to be informed about those?

Yes. BSI needs details of the site(s) where manufacturing processes are performed. This requirement comes from MDR 2017/745, Annex II, point 3C.

If BSI conducted an unannounced audit at the company and found that no actual manufacturing of the device concerned is performed there (it is subcontracted further), and the client had not informed BSI of this, it may raise a major non-conformity (because the information provided about subcontractor locations was inaccurate) and perform another unannounced audit later to witness manufacturing.

Multiple addresses exist for the critical subcontractor. Which ones are required?

BSI requires information for all locations where manufacturing activities take place.

Details for administrative headquarters are not necessary.

Raw material (e.g., metal barstock) is purchased through a broker—is the broker's address sufficient?

No. The addresses of the actual material suppliers are required. This requirement is based on MDR 2017/745, Annex II, point 3C.

Is information about critical subcontractors and crucial suppliers still required for a Class IIa surgical instrument with a very low risk profile?

Yes. These requirements apply regardless of device classification. However, for Class Ir, Im, and Is devices, the required information is limited to the scope of the notified body's responsibility. For example:

- for Class Is devices, only subcontractors related to sterility must be reported.
- for Class Ir devices, only sites performing reprocessing or functional testing activities (as defined in Article 2, Paragraph 39) need to be reported, and only if these occur prior to market placement.
- for Class Im devices, only sites performing critical activities related to the measuring function must be reported.

When should changes to critical subcontractors or crucial suppliers be communicated?

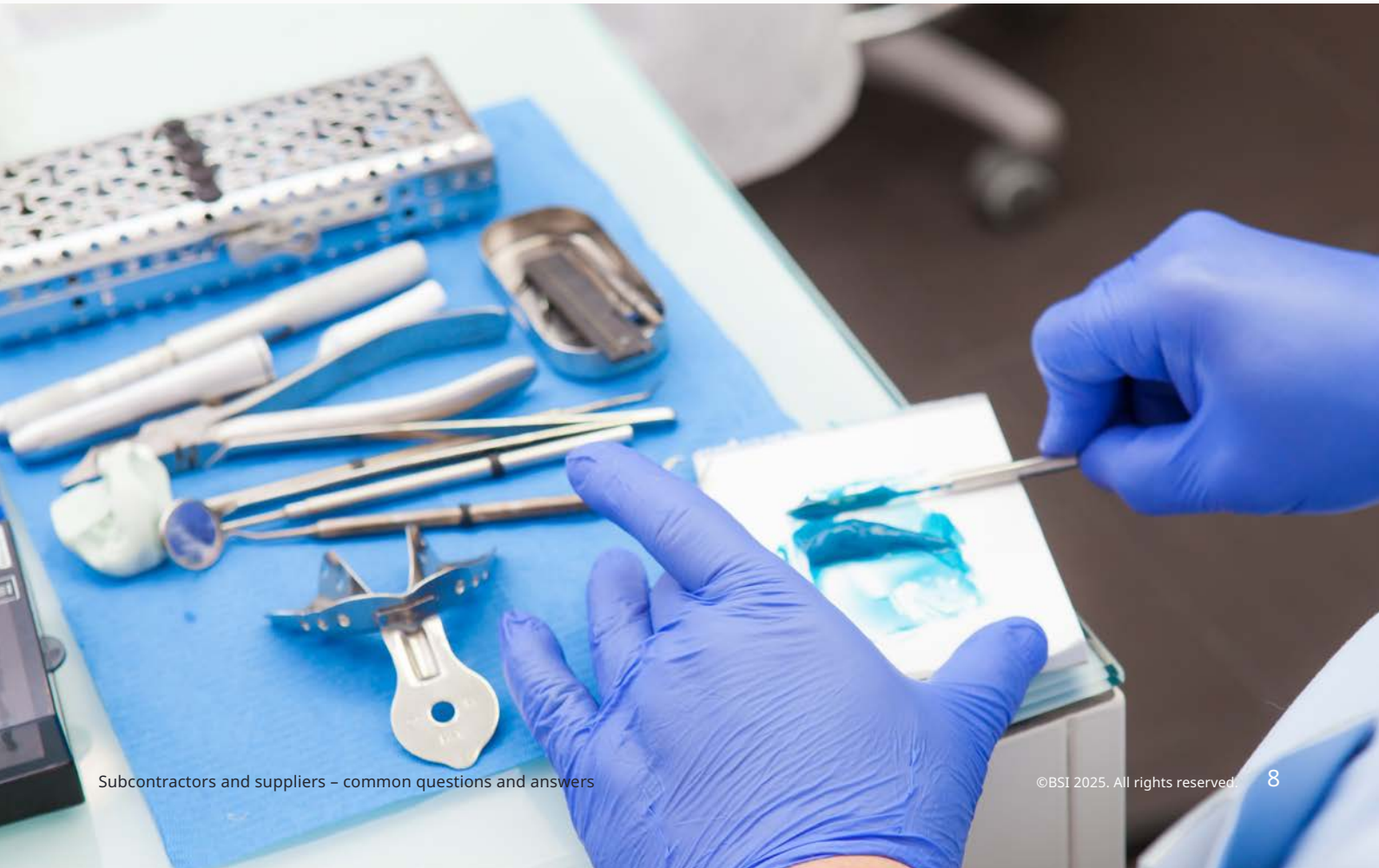
Notification is required whenever such information changes.

Ideally, communication should occur once the full details of the change are known, but prior to implementation.

BSI should be notified using the change notification form to allow determination of whether an assessment is needed.

It is also important to ensure BSI remains informed of site-specific changes (e.g., planned closures, national holidays, or changes to the site contact).

If an unannounced audit is conducted based on outdated information and access to the site is denied (e.g., due to closure), this may result in a major non-conformity and possibly necessitate a repeat audit.



The impact of the changes

What is the impact of changes to critical subcontractors or crucial suppliers?

Due to the complexity of such changes, each case is assessed individually. The following conservative guidance applies:

For devices covered by product certificates (Class III, Class IIb non-Well-established Technology), the following may trigger technical documentation assessment (focused on the change being made):

- introduction of a new critical subcontractor;
- introduction of a new crucial supplier;
- transfer of an existing process to a different critical subcontractor;
- change of location for a critical subcontractor or crucial supplier;
- major process changes at a critical subcontractor;
- modification of inspection criteria;
- change of final cleaning, packaging, or sterilisation location/parameters;
- discontinuation of a critical subcontractor or crucial supplier.

For devices covered by quality certificates (Class IIa, Class IIb WET), the following would trigger an update to the Annex IX Chapter I & III certificate:

- introducing a new critical subcontractor to the certificate;
- introducing a new critical subcontractor to the certificate;
- change of critical subcontractor or crucial supplier location;
- ceasing use of a critical subcontractor or crucial supplier;

The introduction of new machinery, processes or devices at a critical subcontractor also potentially requires conformity assessment, but this is considered on a case-by-case basis.

References

2013/473/EU Commission Recommendation of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

NBOG's Best Practice Guide 2010-1, Guidance for Notified Bodies auditing suppliers to medical device manufacturers.

MEDDEV 2.5/3 Rev 2.

Why choose BSI?

BSI solutions are tailor-made for the orthopaedic and dental devices industry and are delivered by a team of professionals with regulatory, industry and academic expertise.

Our team has a combined average experience of over 300 years in the orthopaedic and dental devices sectors.

Our technical experts are highly competent and knowledgeable on development, design, manufacture, and testing of these medical devices.

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Talk to us

Your partner in progress

BSI Assurance UK Ltd (0086)
Kitemark Court,
Davy Avenue, Knowlhill,
Milton Keynes, MK5 8PP
United Kingdom

+44 345 080 9000

BSI Group The Netherlands B.V. (2797)
Say Building,
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

+31 20 346 0780

BSI Group America Inc.
12950 Worldgate Drive,
Suite 800
Herndon, VA 20170
USA

+1 800 862 4977

Find our services at
bsigroup.com/medical

Email us at
medicaldevices@bsigroup.com

Find us on
LinkedIn