MDR ONLY

Relevant subcontractors and suppliers list

RELEVANT SUBCONTRACTOR / SUPPLIER NAME & LOCATION *(For each subcontractor or supplier that may impact your device, please indicate its name and full address)*	**ACTIVITY UNDERTAKEN** *(Describe the activity of the subcontractor/ supplier and how it impacts your device)*	**JUSTIFICATION FOR SGS NB 1639 NOT VISITING THE SUBCONTRACTOR / SUPPLIER** *(Please provide the certificate held by the subcontractor/supplier, including standards, scope and validity, and explain how you are controlling this subcontractor/supplier)*	**VERIFICATION DURING ON-SITE AUDIT – UPDATE OF INFORMATION** *(To be completed by the SGS Lead Auditor. Record how the manufacturer is controlling subcontractors/suppliers and contracts, allowing access for UNAs)*
NAME: ADDRESS: POSTAL CODE & TOWN: COUNTRY:	ACTIVITY DONE: *(specify the type of process, affected device, final device or component, test and inspection)* RELEVANCE/ CRITICALITY: *(specify the effect on the safety, performance and reliability of the device or its constituent part/s)*	CERTIFICATION: *(standard, OC, certificate number, expiry date)* SCOPE OF THE CERTIFICATE: CONTRACT: *(reference and date)* ASSOCIATED RISK FILE: DATE OF LAST AUDIT: DATE OF LAST EVALUATION: INCOMING INSPECTION: *(100% or sampling)*	• Verify the information provided by the legal manufacturer • Generic supplier/subcontractor risk control measures • Specific risk control measures induced by and applied by the legal manufacturer • Conclude the need for SGS NB 1639 to audit or not audit this contractor/supplier
Name: Address: Postal code and town: Country:	Activity done: Relevance/criticality:	Certification: Scope of the certificate: Contract: Associated risk file: Date of last audit: Date of last evaluation: Incoming inspection:	
Name: Address: Postal code and town: Country:	Activity done: Relevance/criticality:	Certification: Scope of the certificate: Contract: Associated risk file: Date of last audit: Date of last evaluation: Incoming inspection:	
Name: Address: Postal code and town: Country:	Activity done: Relevance/criticality:	Certification: Scope of the certificate: Contract: Associated risk file: Date of last audit: Date of last evaluation: Incoming inspection:	

REVIEW DONE AT CWS STAGE:	Date:	Name:	Signature
REVIEW DONE DURING AUDIT:	Date:	Name:	Signature

SGS

ASSOCIATED GUIDANCE TO COMPLETE THE LIST OF RELEVANT SUBCONTRACTORS AND SUPPLIERS

To allow an efficient review of the purchasing activities in line with ISO 13485 sections 4.1.5 and 7.4 and MDR 2017/745 Article 10 Indent 9(d), we ask you to list your relevant suppliers and subcontractors with associated information. This list must be submitted with your initial application and Medical Device Questionnaire (available on our website), as well as before each audit with your Pre-Audit Client Questionnaire (available on our website). The text in the second row of the table above is added as guidance to help you complete the list and understand what is expected from SGS NB 1639.

The list provided will be reviewed at the application stage, as well as during each on-site audit, to allow our lead auditor to verify provided information and check if relevant controls are in place.

CERTIFICATION OF RELEVANT SUBCONTRACTORS/SUPPLIERS:

All relevant subcontractors/suppliers should have a valid and relevant ISO 13485 certificate (or relevant equivalent certificate, such as ISO 17025 or accreditation for laboratories).

ISO 9001 and GMP certificates can be accepted if duly justified by the manufacturer. This justification will be checked by the lead auditor during the on-site audit.

- Annex 1

  Shows two decision trees that will help you determine which subcontractors or suppliers are relevant to your certification process.

- Annex 2

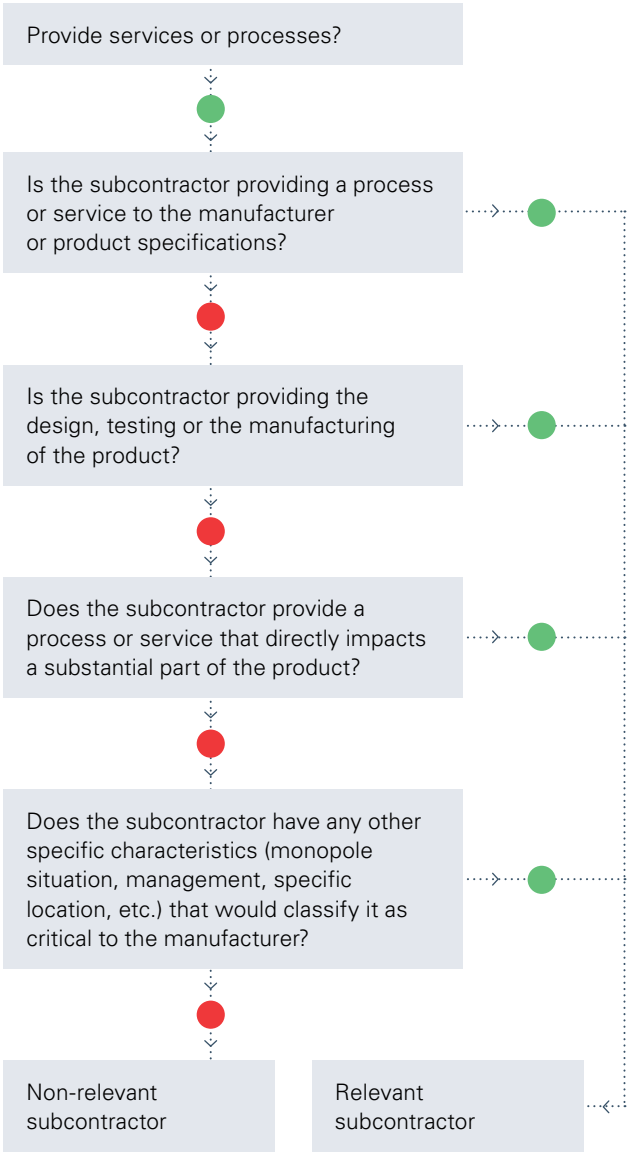
  Shows examples of subcontractors and the suppliers' relevance assessment. The relevance of subcontractors and suppliers shall be considered before risk reduction is applied (certification, contract, audit, incoming inspection, etc.)

- Annex 3

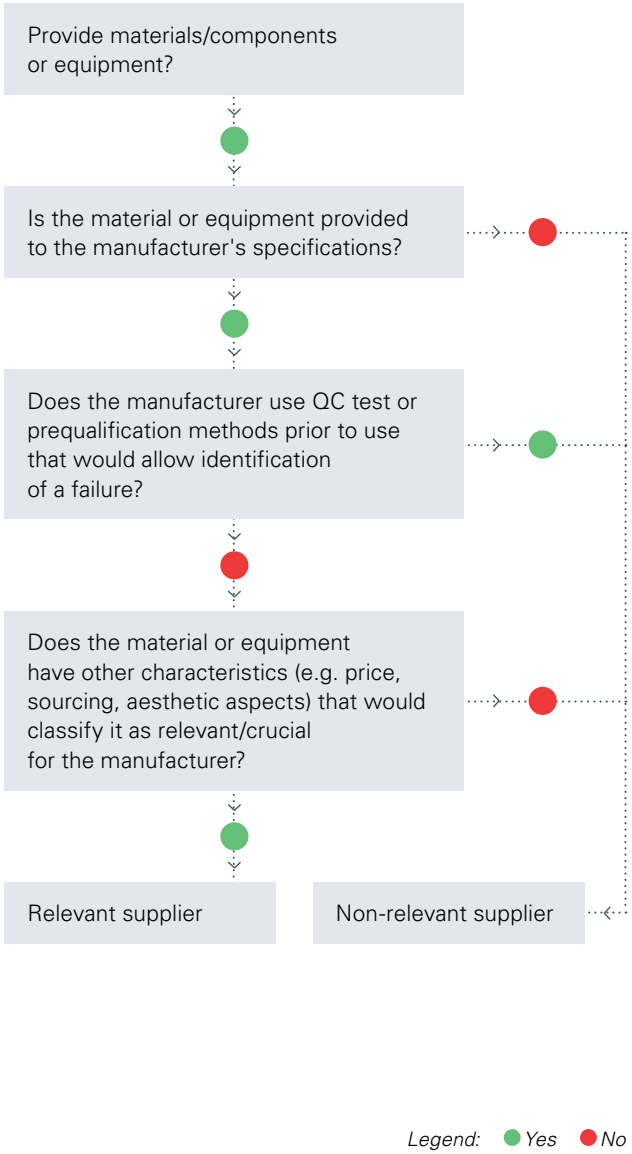
  Shows regulatory references and SGS NB 1639's definition of relevant subcontractors and suppliers.

ANNEX 1: DECISION TREE

DECISION TREE TO DIFFERENTIATE BETWEEN A RELEVANT AND NON-RELEVANT SUBCONTRACTOR



DECISION TREE TO DIFFERENTIATE BETWEEN A RELEVANT AND NON-RELEVANT SUPPLIER



ANNEX 2: EXAMPLES OF CLASSIFICATION AS "RELEVANT SUBCONTRACTOR/SUPPLIER"

- EU representative:

  Provides regulatory services compliance to the manufacturer managed by contract and specifications (i.e. product registration/withdrawal, PMS and vigilance stakeholder, etc.). It may directly impact regulatory and influence the safety compliance of the manufacturer's products.

  → So, it is considered a RELEVANT subcontractor.

- Test laboratory:

  Provides services to the manufacturer to control unreasonable risk to the patient/users (i.e. safety electrical, mechanical, biocompatibility tests, etc.), and/or significant degradation in performance (collateral/specific standard functional performance testing, etc.). It may directly impact regulatory and influence safety compliance of the manufacturer's products.

  → So, it is considered a RELEVANT subcontractor.

- Clinical Research Organization (CRO):

  A manufacturer using a CRO for subcontracting critical processes, such as clinical evaluation or investigation, may have a direct and relevant impact on product clinical and safety aspects.

  → So, it is considered a RELEVANT subcontractor.

- Distributors:

  A distributor who also provides installation or maintenance services/activities for the manufacturer may impact product performance and safety.

  → So, it is considered a RELEVANT subcontractor.

- Metrology/calibration:

  Provides services of periodical verification and calibration of measuring equipment (i.e. weight scale, multi-meter, etc.). It may directly impact product performance and safety.

  → So, it is considered a RELEVANT subcontractor.

- Internal audit:

  An external consultant providing services, such as internal audits (ISO 13485, MDD, MDR, UKCA, MDSAP, etc.), may impact QMS regulatory compliance.

  → So, it is considered a RELEVANT subcontractor.

- Software design:

  An external company providing design software services. If it is considered an input for a substantial part of the product, it may impact product performance and safety.

  → So, it is considered a RELEVANT subcontractor.

- Sterilization:

  An external company providing a sterilization service is considered a subcontractor that may impact product safety.

  → So, it is considered a RELEVANT subcontractor.

- Supplier of critical parts/devices:

  Provides off-the-shelf materials, components, parts or devices that may impact product performance, safety or regulatory compliance.

  → So, it is considered a RELEVANT supplier.

ANNEX 3: REFERENCES AND DEFINITIONS

- "Relevant" (preferred SGS NB 1639 term used) = "critical" or "crucial".

  The term "critical" is the one used under MDD, while "relevant" is the term used under MDR, but they are equal.

- NBOG BPG 2010-1

  Guidance for Notified Bodies auditing suppliers to medical device manufacturers: A critical supplier is a supplier delivering materials, components or services that may influence the safety and performance of the device.

Note: In the context of the audit of medical device manufacturers, a critical supplier is a supplier of a product or service, the failure of which to meet specified requirements could cause unreasonable risk to the patient, clinician or others, or could cause a significant degradation in performance. This can include suppliers of services, which are needed for compliance with QMS or regulatory requirements, e.g. internal audit contractors or Authorized Representatives.

- SGS NB 1639 Internal Definition Glossary (LPMDREG0002)

TERM / ACRONYM	DEFINITION	REFERENCE
Relevant supplier / subcontractor	• Synonym for "critical supplier/subcontractor". • For the purpose of this document, the "product" supplied may be a "process", e.g. a supplier may provide a sterilization process. • The term "supplier" may refer to a "contractor" or "subcontractor". For the purposes of this document, the terms are regarded as synonymous. • A "critical supplier" is a supplier delivering materials, components or services that may influence the safety and performance of the device. • According to ISO 13485:2016, suppliers that may influence applicable "regulatory compliance" should also be qualified as "critical suppliers". • In MDR, the term "relevant" is used instead of "crucial" or "critical". This term is the preferred term in the SGS NB 1639 QMS, for both MDD and MDR. • Note: In the context of the audit of medical device manufacturers, a "critical supplier" is a supplier of a product or service, the failure of which to meet specified requirements could cause unreasonable risk to the patient, clinician or others, or could cause a significant degradation in performance. This can include suppliers of services, which are needed for compliance with QMS or regulatory requirements, e.g. internal audit contractors or Authorized Representatives.	MDR 2017/745 NBOG_BPG_2010_1

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