Relevant subcontractors and suppliers list

***** FOR MDR USE ONLY *****

RELEVANT SUBCONTRACTOR / SUPPLIER NAME AND 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 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 and city/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
REVIEW DONE AT CWS STAGE:	Date	Name	Signature
REVIEW DONE DURING AUDIT:	Date	Name	Signature

ASSOCIATED GUIDANCE TO COMPLETE THE LIST OF RELEVANT SUBCONTRACTORS AND SUPPLIERS

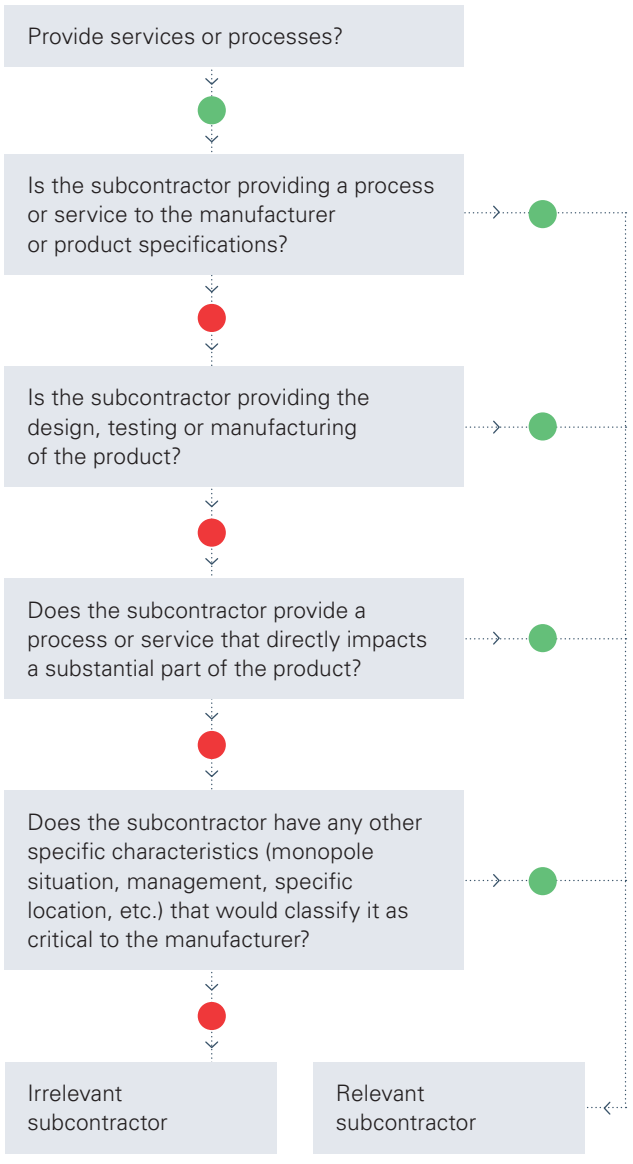
To allow an efficient review of the purchasing activities in line with ISO 13485 Section 7.4 and Medical Device Regulation (MDR) 2017/745 Article 10 Indent 9(d), we ask you to list your relevant suppliers and subcontractors with associated information. You must submit this list with your initial application, together with the Medical Device Questionnaire (available on our website https://www.sgs.com/en/our-services/health-and-nutrition/health-science/eu-medical-devices-regulations-information-center), as well as before each audit with your Pre-Audit Client Questionnaire (also available via the above link). The current text is added as guidance to help you complete the list and understand what is expected from SGS.

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

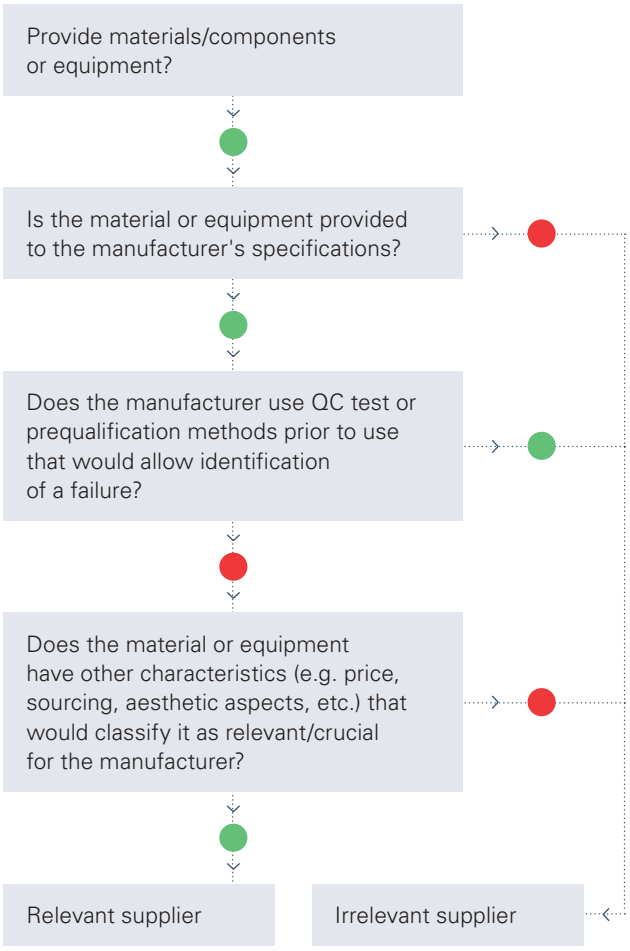
All relevant subcontractors/suppliers should have a valid and relevant ISO 13485 certificate (or equivalent certificate, such as ISO 17025 or accreditation for laboratories). ISO 9001 and GMP certification can be accepted if duly justified by the manufacturer. This justification will be checked by the lead auditor during the on-site audit.

The following decision trees will help you determine which subcontractors or suppliers are considered relevant to your certification process.

DECISION TREE TO DIFFERENTIATE BETWEEN A RELEVANT AND AN IRRELEVANT SUBCONTRACTOR



DECISION TREE TO DIFFERENTIATE BETWEEN A RELEVANT AND AN IRRELEVANT SUPPLIER



Legend: Yes No