YOUR CERTIFICATION PROCESS EXPLAINED

SUMMARY OF KEY POINTS TO FULFIL WHEN SIGNING THE CONTRACT PROPOSAL

- The names and address of the Client and any additional manufacturing site covered by the quality system are specified in this proposal
- The Notified Body 1639 (SGS Belgium) is provided with all the relevant information on the product or product category covered by the procedure
- The documentation on the quality system is available for audit by the Notified Body 1639 (SGS Belgium)
- None of the medical devices, unless expressly described in this proposal, contains a component / element
    - that has or may have a possible pharmacological, immunological, metabolic or antimicrobial activity (according to European Medical Device Regulation 2017/745)
    - that contains animal tissue or derivatives thereof (according to Regulation (EU) No 722/2012)
    - that contains phthalate (according to MDR (EU) 20178/745 annex I section 10.4.3)
    - that contains human cells, blood, tissue or derivatives thereof (according to European Directive 2004/23/EC)
    - that contains nanomaterials (e.g. nano-hydroxyapatite, nano-silver) or may generate nanosized particles (e.g. due to wear-and-tear) according to Commission Recommendation 2011/66/EU of 18 October 2011

The manufacturer confirms that:

- He is fulfilling the obligations imposed by the quality system approved
- He is keeping the approved quality system adequate and effective
- No application has been lodged with any other Notified Body for the same product-related quality system
- The technical documentation which is available for assessment by the Notified Body, either contains or identifies documents defining
    - all the quality management system requirements and therefore no process related to the certified medical devices (design, manufacture, purchase, inspections) is kept hidden or secret from the Notified Body. This is both for the Client and relevant for critical subcontractors or crucial suppliers
    - the full product specifications (composition and components list, both quantitatively and qualitatively) and therefore no product specifications of the certified medical devices are kept hidden or secret from the Notified Body. This concerns purchased aswell as self-fabricated parts / components
- For Annex XI part A of the MDR conformity assessment route a written declaration where appropriate, the technical documentation on the types approved and a copy of the EC type-examination certificates is available for the Notified Body 1639 (SGS Belgium)
- He instigates and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Chapter VII section 2 Article 87 of the MDR (EU) 2017/745 and to implement appropriate means to apply any necessary corrective action
- This undertaking includes an obligation for the Client to notify the competent authorities and Notified Body 1639 (SGS Belgium) of the following incidents immediately upon learning of them:
    - any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88
    - any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country. The reports referred to in the first subparagraph shall be submitted through the electronic system referred to in Article 92