**Cleaning Disinfection Sterilisation EN ISO 17664 Test Questionnaire**

In order to ensure the validity of the test sample selection and the validity coverage of the test results for all your products, it is important that you complete this form accurately and in detail. Our laboratory cannot be held responsible for any delays or losses caused by incomplete or incorrect information.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Manufacturer and address |  | | | | | | | |
| Contact information: (name, email, phone) |  | | | | | | | |
| Name of the Notified Body |  | | | | | | | |
| Applicable regions  (please select) | EU  (MDR) |  | China  (NMPA) |  | United State  (FDA) |  | Others |  |
| List of products to be submitted to the Notified Body(required to cover only those products to which 17664 applies) | *(Please complete in English)* | | | | | | | |
| Product names and models covered by EN ISO 17664 (Reusable products or products requiring user sterilisation prior to use(English) | *(Please complete in both English and Chinese)*  *They canbe listed here or in the annex*  *Note: Based on the products listed, we assist companies in identifying specific samples for testing (with detailed model and specification). Only the selected samples will be tested, other products not tested will be covered in the comprehensive assessment report (i.e. the results will apply to all products covered). To ensure that the samples selected are representative (as the worst case), it is important that companies provide full details of* ***all products*** *to be verified (see the Table of Annex I). Incomplete information may lead to incorrect selection of test samples and thus the test results may not be generalised to all products!* | | | | | | | |
| Product photos | *The photos of the product should be clear (especially the interface should be clearly visible) and in color with all components in the photo.*  *(Please Listed here or in the annexes)* | | | | | | | |
| Product cleaning and sterilisation requirements | *If no specific requirements are mentioned, we default to the usual European methods and test according to these standard methods, which include alkaline detergent (pH 9-10.5), autoclaving (90-93 °C) and steam sterilisation at 134 °C for 5 minutes.*  Please provide product IFU containing the requirements for cleaning and disinfection and sterilisation (preferably in English). | | | | | | | |
| Are the products resistant to ultrasonic cleaning? |  | | | | | | | |
| Is there the maximum times for the product to be cleaned and sterilised? | *If so, what factors determine the maximum times*  *If the company has its own test report on the number of cleaning and disinfection tests, please provide it (add it to the comprehensive assessment report).* | | | | | | | |
| Adapter for product cleaning | *If any, please provide it.* | | | | | | | |
| Description of the differences between the variants or models | *Listed here or in the annexes* | | | | | | | |
| Declaration of authenticity of the entrusting company | The information, samples, accessories and documentation (certificates) provided by our company are all true and valid, and we are willing to assume all legal responsibility for any inconsistencies arising therefrom.  Declared by:  DD/MM/YY | | | | | | | |
| Pre-evaluation by the testing institution | □ Passed  □ Failed  □The following materials are recommended to be supplemented | | | | | | | |

Annex I List of products covered by EN ISO 17664 and the description of characteristics

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| **Product name**  **and model** | **Key materials** | **Is there any internal cavity in the product and if so, in what quantity?** | **Inner cavity diameter** | **Inner cavity length** | **Cavity materials** |
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Annex II Clear photos of representative products from each group