F101-6-MED-MDR Medical Regulatory Certification Agreement for MDR

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PARTIES

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INTRODUCTION

This Certification Agreement (the "Agreement") is made by and between the Notified Body (the "NB") and the Client (the "Client") identified above.

This Agreement supplements the general terms and conditions stated on the Intertek web "Intertek General Terms and Conditions of Services" and the current price list published by the NB.

Clause 1.5 in F101-6 Certification Agreement has a reference to Intertek's web. This link describes seven steps of certification. "Step 2 -Pre-assessment" is not applicable to MDR audits/certifications.
Clause 1.6 in F101-6 Certification Agreement is not applicable for this agreement since audits according to MDR 2017/745 are considered to be regulatory audits.
Clause 2.3 in F101-6 Certification Agreement is amended by the requirements in 2.1 s below, since MDR requires not more than 12 months between audits and also MDR certificates normally have a duration of five years (certification cycle).

This agreement regulates the interaction between the NB and the Client and defines the responsibilities of both parties. This agreement covers the activities of the Notified Body in respect of quality management system auditing, technical documentation review, product test and certification of Client, in conjunction with assessments for conformity with the Medical Device Regulation 2017/745 Annex IX or XI part 10. Conformity assessment activities covered by MDR 2017/745 are concluded in this contract directly between the manufacturer and the notified body and not with any other organisation.

CERTIFICATES

1.1 A certificate is issued to the client once a quality system audit has verified that the organisations quality system complies with the applicable annex to the MDR 2017/745 and when the technical documentation, the so called TD (Technical Documentation according to Annex II in MDR), for a representative selection of the products that the certificate will cover has been reviewed and found to be in compliance with the applicable requirements of MDR 2017/745 and for class III and IIb implant devices, the Design has been reviewed in accordance with Annex IX chapter II. The client shall also undertake to follow these rules.

1.2 The scope of the certificate can be limited to certain activities or product areas, departments, subsidiaries and so on, within the client's organisation.

1.3 The certificate is applicable for the devices which are stated in the product list that is issued as an appendix to the certificate.

1.4 Certificates issued by the NB in respect of Annex IX and XI are normally valid for 5 years, before expiration manufacturers can apply for renewal of certificates. Before the certificate is renewed a recertification audit and technical documentation assessments shall be performed. This application should be submitted approx. 12 months prior to expiration of the certificate but no later than 9 months. A late application may result in an intermission in time between the expiry of the old and issue of the new certificate. The NB cannot guarantee a continuous certification if the extension review reveals major non-conformities against the MDR 2017/745. The NB has the right to limit the validity period of certification if deemed necessary.

1.5 Certificates are not transferable from the Client to another organisation. Change of ownership of a product does not mean that the certificate/s are transferred to the new owner.

1.6 The company whose quality system is certified is entitled to utilize, in his marketing or other external communication, the fact that certification has taken place. The message must not be formulated in such a way that it could be understood that the actual product supplied has been certified.

THE CLIENTS OBLIGATIONS

2.1 The client undertakes to comply with the requirements of MDR Regulation 2017/745 which includes, not limited to, the following:

a) Institute and keep up to date a documented quality system with the scope specified in the certificate. This includes permitting audits to be carried out by auditors appointed by the NB with the frequency that has been decided by the NB.
Failure to maintain a compliant quality management system or product documentation can lead to increased NB surveillance activities, such as additional audit activities or TD for assessments.

b) In a suitable manner integrate the quality system of critical subcontractors and of crucial suppliers with their quality system.

c) Control the quality of services provided and of components supplied and the quality of production thereof regardless of the length of the contractual chain between the manufacturer and the subcontractor or supplier.

d) Inform* the NB about plans for substantial changes in the organizational structure, the quality management system or any activities which could affect the ability of the organization to assure the quality of delivered products. This information shall be supplied to Intertek by using Intertek forms (can be obtained by request to imnb@intertek.com). Only giving oral information to an auditor is not sufficient. Failure to report substantial changes is a violation to this agreement. Changes that can affect an upcoming audit shall be reported at least 45 days prior to the audit or maximum three working days (whichever occurs first) after the audit day has been confirmed from Intertek.

e) Inform* the NB about plans for product changes which affect conformity with the requirements or the conditions for the use of the product. This information shall be supplied to Intertek by using Intertek forms (can be obtained by request to imnb@intertek.com). Only giving oral information to an auditor is not sufficient.

f) Apply* to the NB for addition of new devices to be included in the scope of the certification and when any change to the certificate product category (the scope) or the "MDR – Product list" is required due to the addition of new products or product groups. This information shall be supplied to Intertek by using Intertek forms (can be obtained by request to imnb@intertek.com).

Bullet d, e, f and j can add costs to the client.

g) Notify the relevant Competent Authorities according to current vigilance procedures and reporting criteria of any incidents fulfilling the reporting criteria immediately on learning of them.

h) **Copies of all vigilance reports made to competent authorities shall also be sent to the NB at time of reporting.

i) Institute and keep up to date a systematic procedure to review information about the products placed on the market and to implement appropriate means to apply any necessary corrective action, also known as "Post Market Surveillance".

j) Inform* the NB about changes in ownership or other changes within the certified unit or organisation.

k) Give assessors and experts appointed by the NB access to all facilities, documentation and information which can be of value for the assessment according to the regulation and relevant standards. Visits can be either announced or unannounced and these visits may, if needed, also include product tests. Access to documentation also includes the Technical Documentation so that this can be reviewed in line with the requirement of the regulation. This includes that on request send TD and/or Design Dossiers for review to the NB.

l) Document and file any complaints and any corrective actions taken that affect the certified quality system or the devices. This also applies to complaints and recommendations that are not defined as incidents according to current vigilance guidelines.

m) The NB requires that the top-level quality management system documentation and the technical documentation shall be available in English.

n) The NB requires that documentation relating to the review of periodic safety update reports (PSUR) referred to in Article 86 of Regulation (EU) 2017/745 are available upon request for class IIa, Class IIb. PSUR's for class IIb implants and class III devices are to be submitted to the Notified Body annually. Review of PSUR is charged according to current price list.

o) Remunerate Intertek for the services it has carried out and pay requisite initial and annual service fees.

p) These costs and current pricelist will be updated on a regular basis based on the general cost development for Notified Bodies. The Client will be notified of the updated costs via email and it is the Client's responsibility to ensure that their contact details are valid at all times.

q) Inform* the NB if any separate entity of Intertek has provided consulting services such as: Participation in designing, implementing or maintaining the management system ensuring compliance with the medical device regulations covering:
   - quality management system (or good manufacturing practices);
   - device marketing authorization and facility registration; and
   - medical device adverse events and advisory notices reporting; and
   - product approval testing

   The use of other parts of Intertek services can lead to withdrawal of certificates and termination of agreements.

r) The NB is permitted to obtain client products from the market or from the client to perform tests. The cost for the products and the test shall fall under the client.

s) The client must cooperate with the NB to find suitable dates to perform surveillance and recertification audits. If the time between two regular audits exceeds 12 months the certificate/s can be suspended or withdrawn.

t) At all time have available updated and correct Technical Documentation (TD) for all products under the current valid MDR certificate. The client must adhere to any communicated timelines for sending in and responding to potential issues related to TD assessment. Failure to adhere to communicated timelines can lead to certificate(s) being suspended or withdrawn.

u) For legal manufacturer inside EU there must be a physical address to be able to visit (PO box address or virtual offices are not accepted). For legal manufacturers outside the EU there must be a valid contract, at all time, with a European representative, inside EU.

The Client must have become completely familiar with these rules and accepts them by virtue of signing this agreement.

THE NOTIFIED BODY'S UNDERTAKING

3.1 The NB will supply its services in accordance with the applicable rules for accreditation and notification as defined in Intertek System Certifications management system.

3.2 The NB will verify that the quality system is functioning satisfactory by means of surveillance audits. These audits will take place at regular intervals, but not less than once a year. Extra surveillance audits may be invoked if either the client or the NB considers them necessary.

Technical Documentation "TD" for will be sampled and reviewed as part of the NBs assessment (both initial and surveillance), the review will normally be done off site. The NB may also review the TD and/or the Design Dossier if necessary when application to add new products/product groups to the scope are made or when substantial changes to the product has been done. Addition of products or changes to products may also affect the sampling plan for the Technical Files. The NB is always free to decide to call in further samples of the clients TD. Sampling will be done according to criteria in MDR.

These costs for TD review will be invoiced as per current price list.

3.3 The NB undertakes to treat all information that is put at its disposal as being strictly confidential, but the NB has the right to disclose information to the Competent Authorities, other Notified Bodies and the EU commission if necessary, according the MDR.

3.4 The NB shall enter in the electronic system referred to in Article 57 in MDR any information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates to make such information available to the public.

3.5 The NB might use subcontractors for some of its duties. In the case of the NB using subcontractors for TD assessments or audits this will be disclosed to the client separately, in relation to that specific task.

UNANNOUNCED INSPECTIONS

4.1 The NB is obliged to perform unannounced inspections on the manufacturer premises or if so is necessary also on the premises of critical subcontractors or suppliers in accordance with current EU regulations. This also applies to subcontractors and suppliers further down in the supply chain regardless of the length of the contractual chain between the client and the subcontractor or supplier especially if design & development, manufacturing, testing and other critical processes such as sterilization are outsourced. The frequency and timing of unannounced inspections is completely decided by the NB but shall at least include one unannounced visit per 5-year period (depending on device risk levels and product compliance).

4.2 Unannounced inspections are performed outside the normal surveillance schedule and an unannounced inspection cannot replace a scheduled surveillance audit.

4.3 The NB shall institute a mechanism for the Client to verify the authenticity and validity of any requests to perform unannounced inspections.

4.4 If a visa is needed to visit the client or any critical subcontractor or crucial supplier the client shall assist the NB to obtain a visa in any manner necessary. This could include issuing invitations to visit with date of visit open or similar documentation.

4.5 If the manufacture of devices is very irregular the client shall inform the NB when production is planned for devices falling under the issued certificate.

4.6 If permanent unannounced access to the premises of the client or its critical subcontractors or crucial suppliers is no longer assured, these are grounds for ending the contract and withdrawing the certification.

4.7 The Client is obliged to permit auditors appointed by Intertek immediate access to the facilities and relevant personnel at any time during the facilities normal business hours (observing national holidays) for the purpose of performing unannounced inspections which should include performing or observing the testing of products at either the legal manufacturers site, sub-contractors or if this is not possible perform testing of product from the market as appropriate.
Failure to be able to perform or witness a requested test will constitute an incomplete unannounced audit and leading to additional unannounced audit within the cycle.

The Client shall inform Intertek in writing (mail to imnb@intertek.com) if they are not able to meet this requirement on specific dates at least one month (30days) prior. Due to the nature of unannounced audits, should the auditors turn up and no one is on site the full fee as detailed in 4.9 will be charged.

4.8 The client undertakes to have appropriate agreements with any subcontractor or supplier performing critical operations allowing the Notified Body to perform unannounced visits at the subcontractor's or supplier's facilities. This also applies to subcontractors and suppliers further down in the supply chain regardless of the length of the contractual chain between the client and the subcontractor or supplier.

4.9 The Client shall financially compensate the NB for the performance of any unannounced inspections including, where applicable, the device acquisition, its testing and any security arrangements for the NB's auditors.

An unannounced audit is always at minimum two (2) audit-days plus travel costs. These audit-days and travel costs will be invoiced to the client as per current price list.

REVOCATION OF CERTIFICATES

5.1 The NB can revoke an issued certificate with immediate effect. The NB may also, after assessment of a particular situation, temporarily suspend the certificate until a given remark has been resolved within a given time limit.

5.2 The NB is entitled to publish a decision to definitively or temporarily revoke a certificate. When the certificate is revoked, the client will be deleted from the list of certified clients.

5.3 When a certificate is revoked, the client is entitled to appeal against this measure in accordance with item 10.

5.4 Reasons for revocation include but are not limited to:

a) the client has seriously breached the certification agreement
b) a major non-compliance has been detected in a follow-up audit and requisite corrective measures cannot be expected to be taken
c) the certificate has been utilized for devices or for activities which have not been audited
d) misuse of or misleading references to the certificate or the CE mark such as in advertising material
e) incomplete or untrue information has been supplied at certification audits, surveillance audits, unannounced audits or in the technical documentation (TD)
f) concealing significant changes that have occurred of the devices, in the organization and/or in the relevant quality management system
g) neglecting to carry out improvements which the client has been requested to undertake
h) unsettled debts or unpaid invoices to Intertek
i) bankruptcy, closing down of the business or inability to function in the form that has been audited
j) failure to establish and keep up to date technical documentation (TD), for each device (or device group), that are in line with established regulations and guidelines.
k) divergence found during audits and inspections between samples taken from production and the specifications laid down in the technical documentation (TD)
l) denying auditors access to the facilities and/or personnel for the purpose of performing planned or unannounced audits
m) not accepting the costs related to product tests that the Notified Body plans to do
n) change in status and scope of designation of the Notified Body

5.5 After revocation of the certificate, the client must immediately return* the certificate to the NB. The client must immediately cease to refer to the certificate and inform those affected.

The NB´s RESPONSIBILITY

6.1 Auditors are appointed in accordance with applicable rules with respect to neutrality and objectivity. Clients are, however, entitled to object to proposed auditors with stated reasons. An auditor cannot however be rejected during the course of an audit.

6.2 If the client has well-found objections to the quality and objectivity of the audit, and the objection is accepted by the NB, the NB will conduct a supplementary audit at its own cost, if necessary, using other auditors.

6.3 The NB is not responsible if a third-party declines to recognize an issued certificate, either wholly or partially, and bases his order terms on such circumstances. The same applies to any compensation claims made by customers of the certificate holder, where such customers' expectations on matters of quality have not been fulfilled, or where the certificate issued by the NB is not accepted as viable evidence in disputes such as those involving product liabilities.

6.4 If there are any changes in the NB legal structure or recognition, Notified Body Number or similar the NB will not pay for any damage or loss to the Client following these changes.

INVOICING AND DEPOSIT

7.1 A deposit may be required upon an unfavourable credit report.

7.2 For all Technical documentation review activities, deposits will be invoiced. Work on technical documentation review will only commence once the Client has paid the invoice in full.

7.3 Additional services requested by the Client and/or required to support certification will result in additional charges, invoiced as per current price list. Examples of additional services include the request for letters or other non-standard documents, reviews associated with changes to the quality management system or products and special audits resulting from such issues as not meeting the audit criteria, field complaints, product recalls, or customer reports of poor trends in quality, delivery and/or services or related issues.

7.4 An additional follow up visit will be required if the auditor cannot determine effectiveness during the certification audit. This will be invoiced as per current pricelist.

7.5 All fees associated with the services NB undertakes will be invoiced upon completion of each activity, with the exception of technical documentation review as per 7.2 above.

7.6 Travel expenses and travel time for auditors shall be invoiced as per current price list.

7.7 Terms are net 30 days on invoiced amounts not covered by a deposit.

7.8 Should the Client not pay an invoice in time, the certificate(s) are suspended until invoices are paid in full.

7.9 If the Client cancels any NBs activities without a 30-day notice, NB will invoice the full fee for the planned work.

7.10 Invoices are sent to Client based on current price list. See point 2.1, p) above for more details on the current price list.

REVISION OF REGULATIONS AND STANDARDS

The NB reserves the right to amend these rules with immediate effect – for instance as a result of amended regulations and/or accreditation rules.

CERTIFICATE VALIDATION

The validity of a certificate may be verified by sending a request to at certificate.validation@intertek.com.

APPEALS

10.1 The Client has the right to appeal any decision made by Intertek as specified in GOP208 – Disputes and Appeals Process, posted on Intertek's website at **HTTP://WWW.INTERTEK.COM/AUDITING/MANAGEMENT-SYSTEMS/POLICY/.**

10.2 The original decision made by the NB applies pending the processing of the appeal.

TERMINATION

11.1 Both parties have the right to terminate their collaboration. The notice period for termination is 90 days after received written confirmation. The Client must therefore ensure that their contact details are valid at all times.

11.2 Should the NB find the Client to be in breach of any regulations, directives, legal or contractual aspects; the collaboration will be terminated effective immediately and such termination will be sent to the Client in writing. The Client must therefore ensure that their contact details are valid at all times.

* This information shall be given to the following e-mail address: imnb@intertek.com
** This information shall be given to the following e-mail address: vigilance.reporting@intertek.com

Signing this Agreement constitutes a formal application for MDR conformity assessment with Intertek Medical Notified Body AB. This means that no other applications for the same conformity assessment can be done to another Notified Body. Intertek is obliged to report to EUDAMED of any discontinues under this agreement.

	Notified Body	SunTech Medical Inc.
Signature:	Michael Williams	
Print Name:	Michael Williams	
Title:	VP OPNS/QA/RA	
Date: YYYY-MM-DD	2022-07-18	

Martin Lindvall
Technical Planning Team Leader
Intertek Medical Notified Body

Martin Lindvall Intertek
Aug 10 2022 11:13 AM

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Revision Log		
Revision no.	**Description of change**	**Release date**
0	New document	27-Apr-2018
1	Minor changes to comply with the MDR additional clauses to clint obligantions and NB undertakings.	22-Oct 2018
2	Clarifications on "Intertek services". Added clarification on costs for test. Added req for address. F101-6 clarification.	14-Aug-2019
3	Addition of "renewed a recertification audit and technical documentation assessments shall be performed. This application should be submitted approx. 12 months prior to expiration of the certificate but no later than 9 months" to section 1.4 and clarification to bullet n) about PSUR	12-Nov-2019
4	Minor changes to section 2.1, 2.1 a), 2.1 t) and 4.7 according to OFI #195 and #250 from MDR Process validation feedbacklog.	11-June-2020
1.0	Document revision numbering restarted at 1.0 due to migration to new QMS. Updated intro to align with F101-6. Updated statement with signatures. 2.1d updated.	23-Mar-2021