APPLICATION SUBMISSION FOR SYSTEM CERTIFICATION ACCORDING ISO 13485:2016

Note to the applicant: ISO 13485 requires the management to determine the applicable obligations connected and aspects of the medical products to be handled and / or assessed according to European regulation. The application becomes mandative as contractual condition for the assessment. In order to determine the adequate assessment contract, we mandate the applicant to declare the information correctly. If it becomes aware within the later assessment-procedure that topics have not been declared accordingly, the assessment and the contract must be re-evaluated, charging the effort to the applicant. In order to prevent from this, the applicant is recommended to call in advance for technical advice, to evaluate the correct understanding of the processes for certification and to give correct declaration.

1. INFORMATION ABOUT THE COMPANY / INFORMAZIONI GENERALI DELL'AZIENDA

Company name:			
Contact person:		Role	
Legal office address			
Tax-No/VAT:		Tel/mobile	
SDI / Pec			
e-Mail:		website	

Is legal office also operative site?La sede legale è anche operative? ☐YES ☐NO

please describebelowany involved places in the following pages(vedi pag. successive-elenco siti)

2. REQUESTED SERVICES / TIPO DI ATTIVITÀ RICHIESTA A QS

☐ Certification/ Certificazione ☐ Re-certification / Rinnovo

☐ Transfer from other CAB* / trasferimento della certificazione da altro ente

☐ Pre-evaluation / Pre-audit

☐ other/altro: .....

*IN THE CASE OF TRANSFER FROM ANOTHER BODY it is mandatory to attach a copy of the certificate in Possession, a copy of the previous system's reports, a copy of the current system documentationand complete the transfer audit statement that will be sent by the secretariat (ref. RULE QS QUALITY SERVICES published on the website www.qualityservices.com.mt)

*IN CASO DI TRASFERIMENTO DA ALTRO ORGANISMO è obbligatorio allegare copia del certificato in Vs. possesso, copia dei rapporti dell'organismo precedente, copia della documentazione di sistema in vigore, e compilare la dichiarazione di transfer audit che verrà inviata dalla segreteria (rif. REGOLAMENTO QS QUALITY SERVICES pubblicato sul sitowww.qualityservices.com.mt)

3. INFORMATION ABOUT THE MANAGEMENT SYSTEM / INFORMAZIONI SUL SISTEMA DI GESTIONE

MS exists since/ Sistema di gestione attivo da		Runtime certificate till: Validità del certificato in essere fino a:	
For which standard? Per quale norma?		MS was last certified by: ☐ QS Quality services Ltd ☐ Other Body/altro ente: …….	

QS Quality Services Ltd
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Time plan / audit date (Re-) certification:		Stage-1-audit is necessary ☐ No ☐ Yes, because ☐ Initial certification ☐ Certificate>3 month interrupted
Consultant/ society Consultente/società		
Other/ altro/ note:		

4. INFORMATION ABOUT THE INCLUDED AND EXCLUDED ACTIVITIES BEYOND CERTIFICATION / DESCRIZIONE DELLE ATTIVITA' INCLUSE NELLO SCOPO DI CERTIFICAZIONE	
SCOPE CERTIFICATION REQUIRED / SCOPO DI CERTIFICAZIONE RICHIESTO	
GENERAL COORDINATION OF MAIN BUSINESS ACTIVITY TO A BRANCH FOR THE APPLIED CERTIFICATION: (tick applying boxes)	☐Development ☐ Production ☐ Service ☐ Trading ☐ Finance / Insurance / Administration ☐other ……
BRIEF DESCRIPTION OF ACTIVITIES CARRIED OUT BREVE DESCRIZIONE DELLE ATTVITA' OPERATIVE	
OPERATED BUSINESS ACTIVITIES BUT EXCLUDED FROM THE CERTIFICATION: ATTIVITA' ESCLUSE DALLA CERTIFICAZIONE	

5. PERSONNEL INVOLVED / PERSONALE COINVOLTO			
	No. of person full-time	No. of person part-time	No. of shift/turni
ADMINISTRATION/TOP MANAGEMENT PARTNER/ DIREZIONE			
ADMINISTRATIVE AMMINISTRATIVO			
OPERATIVE PERSONNEL PERSONALE COINVOLTO NELLE ATTIVITÀ/PROCESSI PRINCIPALI			
SISTEMA DI GESTIONE			
MARKETING / COMMERCIALE			

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ATTVITA' SECONDARIE:			
OTHER/ALTRO:			

6. SITES DESCRIPTION / DESCRIZIONE SITI Declaration of any site/joining branch of the company, describe and differentiate the function and relation and operated activities for each position (such as headquarter / internal / management and sales or supplier / external / mechanical production and warehouse, etc.):

Dichiarare ogni sito / ramo di appartenenza della società, descrivere e differenziare la funzione e la relazione e le attività gestite per ogni posizione (es. quartier generale / sito produttivo di un processo / gestione e vendite / assemblaggio o magazzino, ecc.):

Total number of sites to certify n. (numero di siti in totale da certificare):	

Type of site /place / address	**Description of function / relation / activities:**	**Embedede mployees**

OUTSOURCING AND SUPPLIER outsourced activity or subsidiary supply, which might contribute essentially to the scope of certified activities (occasionally attach a list in detail);
attività esternalizzata o fornitura sussidiaria, che potrebbe contribuire essenzialmente alla portata delle attività certificate (allegare occasionalmente un elenco in dettaglio)

Name of site / place	**Description of function / relation / activities:**	**Embeded employees**

DECLARATION OF ANY SITE TO BE ASPECTED AS JOINING PARTY (AS MENTIONED ABOVE) BUT EXCLUDED FROM THE SCOPE OF CERTIFIED ACTIVITIES (OCCASIONALLY ATTACH A LIST OF EXCLUSIONS IN DETAIL):

NAME OF SITE / PLACE	**DESCRIPTION OF FUNCTION / RELATION / ACTIVITIES:**	**EMPLOYEES**

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5. TECHNOLOGIES TO BE RECOGNIZED WITHIN THE ADDRESSED MEDICAL PRODUCTS(TECNOLOGIE UTILIZZATE NELL'AMBITO DEI PRODOTTI MEDICALI)

☐S1 clean room technology (clean room operation, aseptic production, restricted area production, laboratory surrounding)
☐S2 finishing processes (labeling, cleaning, packing, sterilisation)
☐S3 demanding technology (processes technically demanding or with high impact on product as coating, hardening, vacuum / physical / chemical treatment)
☐S4 electronics and software (special requirements towards electronic circuits, handling, qualification, software development and validation, IT, telemetry)
☐S5 development (operational processses to develop new products)
☐S6 processing (operational processes to manipulate semiproducts to final products)
☐S7 compliance (introducer to market, patent keeper, representant for manufacturer, licence handling)
☐S8 production (operational processes generally to manufacture physically in-house / in several branches / supplier, operating metals / plastics / ceramics / fluids)
☐S9 storage and trading (no manufacturing, purchasing and distribution, storage and transportation)
☐S10 health care and service (operative handling or application of product, processes for refurbishment / repair / reworking)

☐ .....

6. CHARACTERISATION OF PRODUCTS HANDLED BEYOND THE MANAGEMENT SYSTEM / DESCRIZIONE E CARATTERISTICHE DEI PRODOTTI INCLUSI NEL SISTEMA DI GESTIONE ISO 13485

ISO 13485 requires to assess the procedures (i.e. for production, processing or handling) connected to medical devices as a managed element. Additionally, the certification body must reflect the characteristics of the operation under means of risk management and within the frame of the MDR requirements in the assessment operation as well (if necessary, attach a list in detail).

Medical device covered from certification	class / rule	Implatable / active	indicate specific process
		☐☐	
		☐☐	
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		☐☐	

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Note: The classification can be derived selecting the appropriate rule from EU- regulation EU 2017-745 app. VIII. This also takes into account the intended use as for implantology or as being active. Special processes are typically to be validated or are defined as of highly innovative or technological content.

Date

Signature/Role

PLEASE ATTACH COMPANY CHAMBER DOCUMENTATION
The company takes responsibility for the correctness and veracity of the information provided.

SI PREGA DI ALLEGARE COPIA DELLA VISURA CAMERALE
L'azienda si assume la responsabilità della correttezza e della veridicità delle informazioni fornite.

TO BE FILLED ONLY BY CENTER BRANCH OF CERTIFICATION BODY /
PARTE RISERVATA ALL'ORGANISMO DI CERTIFICAZIONE

Following evaluations have been performed as respectable activity until now (attach evidences):

☐Company visited at: ……..

☐Check of documentation dated: …….
☐Pre audit at: ……..
☐Expert discussion at: ……..

☐This application was received by sales office.
The definite offer has to be transmitted from center branch to recipient
☐via sales representant or
☐directly to applicant.

application received (by / date): .....

application recorded as (case identification): .....

processed / transmitted to dispatcher by / date):.....

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