INFORMATION ON THE COMPANY

Company: _____

Street, number: _____

Postal code, city/town: _____

Contact person: _____

E-mail: _____

Phone: _____

Fax: _____

Company proprietor: _____

Branch offices / locations (with address): _____

Fields of business / commercial register entry: _____

Manufacturer code / DIMDI code: _____

INFORMATION ON THE RANGE OF PRODUCTS

Product designation: _____ UMDNS code or MD scope: _____

Product description: _____

(Please enclose advertising/ information material.)

Number of generic product groups: _____

Medical field of application: _____

Risk class acc. to MDD Annex IX: _____

Classification rule: _____

Is animal tissue rendered nonviable utilized? ☐ yes ☐ no

Is a pharmacologically active substance used in a product? ☐ yes ☐ no

Does a license exist for this product? (Please enclose license.) ☐ yes ☐ no

A product assessment is required: ☐ yes ☐ no

Product assessments are available for the following products: _____

A product assessment is required for the following products (clinical evaluation, risk analysis, standard conformity test, EMC measurement/evaluation, type examination): _____

DESIRED CONFORMITY ASSESSMENT OR CERTIFICATION PROCEDURE

☐ DIN EN ISO 13485 Exclusions: _____

Outsourced processes: _____

☐ MDD Annex II (Full quality assurance system) excluding section 4
☐ MDD Annex III (EC Type Examination)
☐ MDD Annex IV (EC Verification) Batch size: _____
☐ MDD Annex V (Production quality assurance)
☐ MDD Annex VI (Product quality assurance)

The necessary EC Type Examination certificates are already available: ☐ yes ☐ no

For the following products an EC Type Examination certificate must yet be issued: _____

Additionally, a certification according to ISO 9001:2015 is required: ☐ yes ☐ no

Desired scope: _____

INFORMATION ON THE QUALITY ASSURANCE SYSTEM

Current status

A QM/ QA system has been implemented: ☐ yes ☐ no
Initial certification: ☐ yes ☐ no
Re-certification: ☐ yes ☐ no Please, enclose a copy of the certificate and the last audit report.

☐ acc. to DIN EN ISO 9001 ☐ acc. to DIN EN ISO 13485 ☐ acc. to MDD Annex

Documentation

☐ one quality manual and the same process instructions for all locations
☐ one quality manual, but different process instructions for different locations
☐ different quality manuals and different process instructions for the different locations

Do you use consultancy services regarding your QM system? ☐ yes ☐ no

Business locations related to the product

Is the whole company to be audited? ☐ yes ☐ no
Which divisions are not to be certified? _____
Please, enclose the organizational chart.

Number of employees in / location:	1. Headquarters	2. Production facility
Development		
Manufacturing		
Quality assurance		
Regulatory affairs		
Customer services		
Material / purchasing / logistics		
Distribution		
Administration		

Number of suppliers associated with the product (Supplier: supplies assemblies / components acc. to his own specifications):	
Number of subcontractors (Subcontractor: supplies services, assemblies / components acc. to the specifications of the manufacturer):	

	Company address / company profile	Kind of involvement (e.g. certified, audited by the client, included in the client's QA, incoming goods inspection, ...)
Quality assurance/ testing		
Development		
Documentation		
Manufacturing		
Assembly		
Sterilization		
Software development		
Others		

Place, date

Submitted by