PUBLIC PROCEDURE FOR THE APPLICATION

Issue: ASA DM – A. ROMANIELLO
Verification: QA – M. CACCAMISI
Approval: QA – M. CACCAMISI

Certiquality Srl | C.F. e P.I. 04591610961 | R.I. MI 04591610961 | R.E.A. MI 1759338 | Ph. +39028069171 | certiquality.it | info@certiquality.it

SUMMARY

eCertiquality Srl | C.F. e P.I. 04591610961 | R.I. MI 04591610961 | R.E.A. MI 1759338 | Ph. +39028069171 | certiquality.it | info@certiquality.it

1. FOREWORD

This document provides the guidelines for submitting to CERTIQUALITY an application to start the verification process of the compliance of a medical device, or a group of medical devices, pursuant to the Regulation (EU) 2017/745.

2. PRELIMINARY INFORMATION

The Organisation may ask to CERTIQUALITY a certification offer for the CE marking of a medical device by providing the information preliminary to the submission of the application by filling-in the MOD DOM DM REG_E form.

The same methods also apply if the Organisation intends to transfer to CERTIQUALITY a certification already issued by another Notified Body.

The MOD DOM DM REG_E includes, in particular, the request for information concerning:

- product description;
- the scientific rationale on the basis of which the product for which the certification has been required has been classified as medical device;
- intended use;
- mechanism of action/operation modes;
- duration of use;
- classification rule;
- compliance assessment procedure chosen;
- special characteristics (e.g. sterility, measuring function, presence of medicine);
- the sites of the manufacturer or of the suppliers/sub-suppliers that are included in the quality management system of the manufacturer.

Moreover, with the filling-in of the MOD DOM DM REG_E form, CERTIQUALITY asks the Organisation:

- to formally state to have withdrawn the application submitted to another notified body, if any, before it had taken a decision concerning said application,
- to provide formal information about any previous applications concerning the same compliance assessment that were refused by another Notified Body.

The information contained in the MOD DOM DM REG_E is reviewed by CERTIQUALITY to preliminary determine, if:

- the product is regulated by the Regulation 2017/745,
- the product is correctly classified in accordance with Annex VIII of the Regulation 2017/745,
- the Organisation has chosen a conformity assessment procedure consistent with the product classification,
- the product is included within the designation of CERTIQUALITY as Notified Body.

CERTIQUALITY issues the offer only if:

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- the MOD DOM DM REG_E has been completed in all its parts and it has been signed and stamped by the Legal Representative or by a person authorized by the applicant Organisation,
- the applicant has sent evidence of payment of the fee due for the preliminary activities and
- the review of preliminary information has had a positive outcome.

Should the information review have a negative outcome, CERTIQUALITY informs the Organisation, asking for clarifications and supplementary information, if need be.

The offer is issued in the Organisation's name and sent to it, together with the REG DM_E 'REGULATION FOR ISSUE AND MAINTENANCE FOR MEDICAL DEVICE CE MARKING CERTIFICATION ACCORDING TO REGULATION (EU) 2017/745.

The REG DM_E defines the relationship between CERTIQUALITY and the Organisation wishing to achieve the certification for the CE marking of the medical device in compliance with the Regulation (EU) 2017/745. The implementation of the REG DM_E is verified by the Committee for Safeguarding Impartiality, appointed by the Board of Directors of CERTIQUALITY, in compliance with the provisions of the Accreditation Standard of Certification Bodies UNI CEI EN ISO/IEC 17021–1.

The REG DM_E comprises all information regarding the process to achieve certification, transfer included, as well as the obligations related to its maintenance, change, extension and renewal.

3. SUBMISSION OF THE CERTIFICATION APPLICATION

CERTIQUALITY considers the set of following documents as certification application:

- copy of the MOD DOM DM REG_E completed in all its parts and signed by the applicant Organisation,
- copy of the offer signed for acceptance by the applicant Organisation,
- copy of the 'Regulation for awarding and maintenance of the certification for the CE marking of medical devices in accordance with the Regulation (EU) 2017/745' (REG DM_E), signed for acceptance.

In order to start the compliance assessment process, the Organisation shall send to CERTIQUALITY the following documents:

- copy of the offer signed for acceptance by the Legal Representative,
- copy of the 'REGULATION FOR ISSUE AND MAINTENANCE FOR MEDICAL DEVICE CE MARKING CERTIFICATION ACCORDING TO REGULATION (EU) 2017/745' (REG DM_E), signed for acceptance by the Legal Representative,
- documentation regarding the application for the assessment of the quality management system (pursuant to section 2.1 of the Annex IX to the Regulation 2017/745),
- technical documentation (pursuant to Annex II to the Regulation 2017/745),
- technical documentation concerning post-market surveillance (pursuant to Annex III of the Regulation 2017/745),

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- documentation concerning clinical evaluation and post-market clinical Follow-up (pursuant to Annex XIV of the Regulation 2017/745),
- specific documentation for class III medical devices or implantable medical devices:
  - copy of the implant card and information to be supplied to the patients (pursuant to clause 18 of the Regulation 2017/745);
  - summary of safety and clinical performance (pursuant to clause 32 of the Regulation 2017/745),
- any other documents that are considered to be useful to demonstrate the compliance of the medical device, or group of medical devices, with the requirements of the Regulation (EU) 2017/745. We recall, as an example, the documents prepared by the former Notified Body (evaluation reports of the technical and clinical documentation and evaluation of the quality management system), that can be made available in the event of certification transfer.

4. CERTIFICATION RENEWAL

The Organisation shall send to CERTIQUALITY the renewal application within the deadline set up by the Regulation REG DM_E 'REGULATION FOR ISSUE AND MAINTENANCE FOR MEDICAL DEVICE CE MARKING CERTIFICATION ACCORDING TO REGULATION (EU) 2017/745', by filling-in the MOD DOM DM REG_E.

On the basis of the information received, CERTIQUALITY issues a renewal offer.

In order to start the renewal process of the certification, the Organisation shall send to CERTIQUALITY the documents listed in section 3. In the event of the renewal of a EU assessment certificate of technical documentation, the mentioned documents shall be completed with a summary of the modifications and scientific results regarding the medical device prepared in accordance with section 4.11 of the Annex VII to the Regulation 2017/745.

5. CHANGES AND EXTENSIONS OF THE CERTIFICATION

Pursuant to the provisions of the Regulation (EU) 2017/745, to which reference is made in the REG DM_E, the Organisation undertakes to inform CERTIQUALITY about:

- any plan for substantial changes to the quality management system, or the device-range covered,
- any changes to the approved design of the device,
- any changes to intended use including clinical claims or intended user,
- any changes to substance used for the manufacture of a device and subject to the procedures referred to in point 5 of the Annex IX of the Regulation (EU) 2017/745.

The communication to CERTQUALITY must be made by filling-in the MOD DOM MCH REG E, accompanied by a formal communication containing the details of the information notified.

The Organisation undertakes to wait for CERTIQUALITY approval prior to implementing the communicated change.

On the basis of the information received, CERTIQUALITY issues the offer to assess the change.

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In order to start the assessment process of the change, the Organisation shall send to CERTIQUALITY the documents listed in section 3, or part of them, as per agreement with CERTIQUALITY.

6. LANGUAGE REQUIREMENTS

CERTIQUALITY requests that the communications and technical documentation as well as quality management system documents are drawn up in English.

7. REQUEST FOR INFORMATION

For any inquiries please contact CERTIQUALITY's Medical Devices Sector at the following e-mail address: dispositivimedici@certiquality.it

8. REVISION MATRIX

EDITION	DESCRIPTION OF CHANGE
03	§ 5 inserted reference to form MOD DOM MCH REG_E.

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