Appendix E

Extension of EC certificates

Product Service

Manufacturer:

Application identification:

Certificate type covered:

☐ EC quality system certificate (I1, I2 (AIMDD) as well as G1, G2, G3 (MDD) and V1, V2 (IVDD)) or

☐ EC product-related certificate (I5, I7 (AIMDD) as well as G5, G5AO, G7, G7AO (MDD) and V5, V7, V9 (IVDD))

Certificate number:

Valid until:

Please enclose copy of certificate.

Extension of EC quality system certificates

I1, I2 (AIMDD) as well as G1, G2, G3 (MDD) and V1, V2 (IVDD)

Please provide information about devices, manufacturing sites and critical suppliers by submitting Appendices A and B, and, if applicable, C.

Is the certificate to be extended associated with a certificate in accordance with AIMDD Annex 3, MDD Annex III or IVDD Annex V?	☐ Yes ☐ No If **yes,** please enclose copies of the valid certificates.
Have any associated certificates been issued by other Notified Bodies?	☐ Yes ☐ No If **yes,** please enclose copies of the valid certificates from other Notified Bodies.
Do you use OEM products?	☐ Yes ☐ No If **yes,** please enclose copies of the valid certificates issued by Notified Bodies.
Have there been any significant changes since the last audit which have not been submitted as change notifications yet?	☐ Yes ☐ No If **yes,** please submit a separate application for this change/these changes.

Please submit the following document:

A report containing information on any changes to conformity assessment criteria since issue or most recent certificate extension. In case of changes please also describe to which extent.
The report shall include results of the evaluation of:
- Changed or new quality standards (e.g. EN ISO 13485, EN ISO 14971)
- Changed or new applicable regulations (e.g. Directives)
- Statement whether the classification of the products is still correct

Appendix E

Extension of EC certificates

Product Service

Manufacturer:

Application identification:

Extension of EC product-related certificates

I5, I7 (AIMDD) as well as G5, G5AO, G7, G7AO (MDD) and V5, V7, V9 (IVDD)

Please provide information about devices, manufacturing sites and critical suppliers by submitting Appendices A and B, and, if applicable, C.

Have you submitted any change notification within the last 5 years?	☐ Yes ☐ No If **yes,** please list the submitted change notifications and provide the relevant approval page. ☐ *See Appendix F*
Have you implemented insubstantial changes to the product?	☐ Yes ☐ No If **yes,** please list these insubstantial changes with a brief description of the respective change. ☐ *See Appendix F*
Is the certificate to be extended associated with a certificate in accordance with AIMDD Annex 5, MDD Annex V or VI or IVDD Annex VII which was issued by another Notified Body?	☐ Yes ☐ No ☐ n/a If **yes,** please enclose copies of the valid certificates issued by other Notified Bodies.
Please provide the certificate number(s) of the relevant EC Quality System certificates issued by TÜV SÜD here:	
Do you use OEM products?	☐ Yes ☐ No If **yes,** please enclose copies of the valid certificates issued by Notified Bodies and the relevant reports.
Please list all related field safety notices (FSN) and field safety corrective actions (FSCA) as well as incidents in the past certification period, indicate the number of devices sold, and give reasons for any ongoing investigations.	☐ No FSN/FSCA ☐ No incidents ☐ *See Appendix F*
Please list all product-related complaints concerning the devices listed on the certificate and their evaluation.	☐ No complaints ☐ *See Appendix F*
Please provide a clarification/explanation if the list of devices to be extended (Appendix A) is different to the earlier certification.	☐ No differences ☐ *See Appendix F*

Appendix E

Extension of EC certificates

Product Service

Manufacturer:

Application identification:

Extension of EC product-related certificates
I5, I7 (AIMDD) as well as G5, G5AO, G7, G7AO (MDD) and V5, V7, V9 (IVDD)

Please submit the following documents:

Mandatory for all:

1. **A report** containing information about changes of the product related to the conformity assessment criteria after the previous certification. The report shall demonstrate the compliance with the requirements of the Directives for the devices involved, taking into consideration the current state of the art including:
   - Experience gained from the devices in the post-production phase including comparable products in the market (post-market surveillance)
   - Change of suppliers, subcontractors
   - Modifications of production or test methods
   - New experience regarding materials, components etc. used, including biocompatibility
   - Reference to the updated risk management file as listed under 2
   - Risk assessment in relation to new medical treatments and medical technology (benefit risk ratio for the patient)
   - Experience from changes of the updating of the essential requirements
   - Results of new clinical investigations and/or the post marketing clinical follow up including results of comparable products in the market (updated clinical evaluation)
   - Modifications according to regulatory changes

2. **Updated documents** to be attached to the report:
   - Checklist of essential requirements
   - Risk management file
   - Clinical evaluation including copy of relevant scientific literature quoted
   - Instructions for use/labelling
   - List of standards applied (harmonized and non-harmonized standards), Directives and other legal documents

3. A **table of contents** of all documents submitted for the renewal process, including any cross references to any previously submitted data held by TÜV SÜD.

Mandatory, if the device contains a medicinal product or an active pharmaceutical ingredient (API), or if the device is assisted by human blood derivatives:

A **standalone document** containing the following information:

- A justification for the use of the medicinal product, or the active pharmaceutical ingredient (API), or the human blood derivatives for each product type
- A rationale why a re-consultation of the relevant competent authority since the last EC certificate extension process was not deemed necessary
- A statement that there have been no changes made that may have affected the usefulness of the ancillary substance

Please note: Even in case no re-consultation is necessary, TÜV SÜD Product Service GmbH must submit a list of updated documentation from the design dossier file including an updated statement on the usefulness of the medicinal substance in the device to the initially involved competent authority [NBOG BPG 2014-1].

Appendix E

Extension of EC certificates

Product Service

Manufacturer:

Application identification:

Extension of <u>EC product-related certificates</u>
I5, I7 (AIMDD) as well as G5, G5AO, G7, G7AO (MDD) and V5, V7, V9 (IVDD)

Mandatory for medical devices utilizing TSE relevant animal origin material:
An **updated justification** for the use of animal tissue or derivative, including a comparison with lower risk tissues or synthetic alternatives under consideration of the clinical benefit, and an identification of any changes made since the issue of the original certificate (or last EC certificate extension) that could impact the TSE risk.

Please note: Even in case no re-consultation is necessary, TÜV SÜD Product Service GmbH will inform the competent authority (via ZLG) about the final extension decision and that the TSE risk has not increased.

Have there been any significant changes which have not been submitted as change notifications yet?

☐ Yes ☐ No
If **yes,** please submit a separate application for this change/these changes.