

Service Descriptions

HMV Service: Support in registering with the German Hilfsmittelverzeichnis (HMV) as recognized by Germany's health insurance companies

- Initial testing for product conformity in compliance with the requirements and quality standards in place for the Medical Aids Listing (HMV) as recognized by Germany's health insurance companies
- Preparing a list encompassing all documents that have to be submitted
- Assessing that the documentation submitted, including documentation submitted at a later date, is complete and applicable – not included in this is an assessment of studies designed to prove the therapeutic use of new products (client to receive a deviation list where appropriate)
- Communicating with test centres
- Organising and carrying out medical product registration with the IKK Federal Association
- Preparing the registration package
- Submitting documentation
- Communicating with associations and contact person in the event of queries

CE Service: Preparing CE Documentation

- Set-up the document structure
- Preparing the classification protocol and selecting the conformity assessment procedure
- Formally preparing the declaration of conformity
- Preparing the check list for "essential requirements"
- Preparing risk analysis, including proof of standards (see below for details)
- Providing support for the conformity assessment procedure (CE marking) and for communicating with the Notified Body where necessary
- Optional: preparing instructions for use, markings, and flyers, etc. (see details below)

CE Service: Preparing Instructions for Use

- Preparing the required text copy
- Incorporating company specific layouts in accordance with instructions from the manufacturer
- Preparing and incorporating required diagrams and photographs

CE Service: Preparing Risk Analysis

- Preparing the process description (incorporated into QM system where necessary)
- Preparing the description protocol in accordance with DIN EN ISO 14971 annex A
- Preparing the features protocol in accordance with DIN EN ISO 14971 annex D
- Preparing the proof of standards
- Preparing analysis tables and acceptance matrix preparation of the management report and proof structure

CE Service: Clinical Assessment

- Moderating execution of a clinical assessment for the relevant product in conjunction with competent representatives from the manufacturer
- Structuring the results from the clinical assessment, as well as final documentation

CE Service: Sterilisation Validation

- Defining the requirements for sterilisation validation
- Co-ordinating sterilisation validation

Support for International Approvals

- Initial checking for product conformity in accordance with country-specific requirements
- Preparing a list encompassing all documents that have to be submitted
- Checking and assessing that documentation submitted is complete and applicable (client to receive a deviation list where appropriate)
- Communicating with test centres
- Organising and carrying out the approval procedure
- Submitting approval documentation
- Contact person in the event of queries

QM Service: Support in adapting and implementing a QM system

- Providing a staff member for on-site work
- Analysing existing structures
- Documented adaptation and implementation of a QM system in accordance with ISO 9001 or ISO 13485
- Preparing QMHs and providing support for their implementation
- Conducting internal audits
- Providing assistance during certification audits

EAR Registration (WEEE code) – German National Register of Electrical and Electronic Waste

- Initial assessment of the device registration obligation
- Preparing questionnaire to collect data for registration purposes
- Carrying out on-line registration with EAR
- Contact person for further questions and quantity updates

EU Authorised Representative (Germany)

- Assuming responsibility for complying with official registration obligations
- Contact person for regulatory matters
- Co-ordinating and forwarding relevant information

Testing: Expert Review (carried out by sub-contractor)

- Preparing assessment forms/quality control plans
- Testing carried out by experts at a suitable establishment
- Test monitoring
- Preparing a written review

Testing: Expert Review – with MAL

This cost will apply for the expert review only if it is ordered in addition to the MAL service.

Testing: Expert Review - without MAL

This cost will apply for the expert review in cases where the MAL service is not ordered.

Testing: Skin Tolerance Testing (carried out by sub-contractor)

- Testing in accordance with DIN EN ISO 10993-5
- Assessment*) in accordance with DIN EN ISO 10993-1

*) The assessment may require further tests, which will lead to additional costs.

Testing: Low Flammability Testing (carried out by sub-contractor)

- Testing in accordance with DIN EN 1021-1/-2 or
- Testing in accordance with DIN EN 597-1/-2

Testing: Microclimate Testing (carried out by sub-contractor)

- Subject testing (bandages and orthoses, etc.) or
- Testing in accordance with PM 11-3 test method (anti-decubitus products)

Consultancy & Advisory Service: BEO Berlin will consult and advise manufacturers of medical products

- within the framework of carrying out a conformity assessment procedure in accordance with European Directive 93/42/EEC for medical products,
- in preparing instructions for use, risk analyses and other product-related documents,
- in preparing a QM system, and
- in product registration with health insurance companies and other authorities
- BEO Berlin does not provide legal advice/consultancy services.

Assessment: Assessing studies designed to prove therapeutic use

- Assessing the study design (recommended prior to study launch)
- Assessing applicability of the documentation presented in terms of applying for a new product to be entered in the Medical Aids Listing (MAL) as recognized by Germany's health insurance companies

Assessment: Assessing Technical Documentation

- Assessing the client's technical documentation to ascertain applicability within the framework of a conformity assessment procedure in accordance with EC Directive 93/42/EEC
- Preparing a written assessment protocol
- Preparing a written action plan

Seminars and Training

- In-house seminars on client-specific topics
- Seminars and training on the latest issues relating to MP requirements, MP approval and QM

Further services available on request.

BEO Berlin does not provide legal advice/consultancy services.