Notified Body Operations Group (NBOG)

NBOG Documents

In the light of NBOG's terms of reference – to identify and promulgate examples of best practice to be adopted by both Notified Bodies and those organisations responsible for their designation andcontrol – NBOG has produced the following guideline:

Designating Authorities Handbook

Designating Authorities Handbook EN
da_handbook.pdf
PDF-Dokument [681.8 KB]

Designating Authorities Handbook DE
da_handbook_de.pdf
PDF-Dokument [679.8 KB]

Designating Authorities Handbook FR
da_handbook_fr.pdf
PDF-Dokument [745.1 KB]

This Handbook has been designed to be a Best Practice Guide or a practical aid for Designating Authorities and their staff. It provides guidance to authorities on the execution of theirresponsibilities for the designation, monitoring and control of Notified Bodies in the medical devices sector. It is based on a variety of guidance documents produced by various organisations as wellas specific material produced by NBOG. It is anticipated that it will change from time to time as required.

New documents produced by NBOG will be published as documents of

NBOG's Best Practice Guide

These documents provide guidance on specific aspects related to the activities of Notified Bodies

NBOG documents for Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR)

The applicability of Best Practice Guides (BPGs) covering requirements set out in the new medical devices Regulations are contingent upon endorsement by the Medical Device Coordination Group(MDCG). In particular where its involvement is referred to in these BPGs, it must be emphasised that the MDCG should ultimately agree on the relevant steps and deadlines.

Number	Title	Publication
NBOG BPG 2017-1 rev.1	Designation and notification of conformity assessment bodies	Nov 2017

NBOG Forms

Number	Title	Publication
NBOG F 2017-1 rev.2	Application form to be submitted by a conformity assessment body when applying for designation as notified body under the medical devices Regulation (MDR)	Nov 2017
NBOG F 2017-2 rev.2	Application form to be submitted by a conformity assessment body when applying for designation as notified body under the in vitro diagnostic devices Regulation (IVDR)	Nov 2017
NBOG F 2017-3	Applied-for scope of designation and notification of a Conformity Assessment Body – Regulation (EU) 2017/745 (MDR)	Nov 2017
NBOG F 2017-4	Applied-for scope of designation and notification of a Conformity Assessment Body – Regulation (EU) 2017/746 (IVDR)	Nov 2017
NBOG F 2017-5	Preliminary assessment report form – Regulation (EU) 2017/745	tbt
NBOG F 2017-6	Preliminary assessment report form – Regulation (EU) 2017/746	tbt

NBOG documents for medical device directives 90/385/EEC, 93/42/EEC and 98/79/EC

Number	Title	Publication
NBOG BPG 2016-1	(Re-)designation of notified bodies: Process for joint assessments	Jun 2016
NBOG BPG 2014-3	Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System	Nov 2014
NBOG BPG 2014-2	Guidance on the Information Required for Notified Body Medical Device Personnel Involved in Conformity Assessment Activities	Nov 2014
NBOG BPG 2014-1	Renewal of EC Design-Examination and Type-Examination Certificates: Conformity assessment procedures and general rules	Nov 2014
NBOG BPG 2010-3	Certificates issued by Notified Bodies with reference to Council Directives 93/42/EEC, 98/79/EC, and 90/385/EEC	Mar 2010
NBOG BPG 2010-2	Guidance on Audit Report Content	Mar 2010
NBOG BPG 2010-1	Guidance for Notified Bodies auditing suppliers to medical device manufacturers	Mar 2010
NBOG BPG 2009-4	Guidance on Notified Body‘s Tasks of Technical Documentation Assessment on a Representative Basis	Jul 2009
NBOG BPG 2009-3	Guideline for Designating Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessment **Note:** Please note that the current scope expressions (MD / MDS codes) can be found in the respective notification forms below.	Mar 2009
NBOG BPG 2009-2	Role of Notified Bodies in the Medical Device Vigilance System	Mar 2009
NBOG BPG 2009-1	Guidance on Design-Dossier Examination and Report Content	Mar 2009
NBOG BPG 2006-1	Change of Notified Body	Nov 2008

NBOG Checklists

Number	Title	Publication
NBOG CL 2010-1	Checklist for audit of Notified Body’s review of Clinical Data/Clinical Evaluation	Mar 2010

NBOG Forms

Number	Title	Publication
NBOG F 2014-1	Application form to be submitted when applying for designation as a notified body	Nov 2014
NBOG F 2014-2	Qualification of personnel (see NBOG BPG 2014-2) **Note:** After filling in the applicant but **before** handing it out to the personnel the form needs to be protected with a password to prevent changes. (See Microsoft support on the internetfor instructions.) This document includes editorial changes made in 06/2016!	Jun 2016
NBOG F 2012-1	Notification form – Directive 93/42/EEC	Jan 2013
NBOG F 2012-2	Notification form – Directive 90/385/EEC	Jan 2013
NBOG F 2012-3	Notification form – Directive 98/79/EC	Jan 2013
NBOG F 2010-1	Certificate Notification to the Commission and other Member States	Mar 2010

(Probably download required prior to use of the forms)

For comments to the Designating Authorities Handbook and the other NBOG documents or suggestions for amendments, please contact your national NBOG representative or the Chair of NBOG.

These documents provide guidance on specific aspects related to the activities of Notified Bodies.
Please note that hyperlinks contained in the following documents are valid only when the documents are published. Subsequent changes of such links will not be updated.