Ordinance on the Database-supported Information System on Medical Devices of the German Institute for Medical Documentation and Information (DIMDI Ordinance – *DIMDIV*)

of 10th May 2010

of 4th December 2002 (Federal Law Gazette (FLG) I p. 4456), last amended by Article 1 of the Ordinance of 10th May 2010 (FLG I p. 542).

Section 1
Scope

The present Ordinance governs the acquisition of the data which are necessary for the database-supported information system on medical devices, their transmission to the German Institute for Medical Documentation and Information (DIMDI), as well as the processing and use of the data stored in this information system.

Section 2
Electronic notifications and applications

(1) Notifications pursuant to Sections 25 and 30, sub-section 2 of the Act on Medical Devices are to be made by means of data transmission via the central data collection system of the German Institute for Medical Documentation and Information according to the Annexes to this Ordinance.

(2) Sub-section 1 applies accordingly to:

1. Notifications pursuant to Section 18, sub-section 3, number 1, Section 22c, sub-section 1, as well as Section 23a of the Act on Medical Devices, as well as pursuant to Section 8, sub-section 2, sentence 1 of the Ordinance on the Clinical Investigation of Medical Devices,

2. Applications pursuant to Section 22, sub-section 1, sentence 1, Section 22a, sub-section 1, sentence 1, Section 22c, sub-section 2 and Section 24 of the Act on Medical Devices, as well as pursuant to Section 7, sub-section 1 and Section 8, sub-section 2, sentence 4 of the Ordinance on the Clinical Investigation of Medical Devices.

(3) A nomenclature specified by the German Institute for Medical Documentation and Information through the central data collections system shall be used for the designation of medical devices. The technical modalities of the data collection and transmission shall be published by the German Institute for Medical Documentation and Information on its website.

Section 3
Central data collection system for the receipt of applications pursuant to the Act on Medical Devices

(1) At the German Institute for Medical Documentation and Information, the prerequisites shall be created to receive notifications pursuant to Section 18, sub-section 3, no. 1, Sections 25 and 30, sub-section 2 of the Act on Medical Devices for the competent authorities, centrally, by means of an internet-based data collection system. The notifications shall be automatically assigned to the competent authorities and the latter will be immediately informed that a notification has been received.

(2) The competent authorities shall examine the data posted pursuant to Section 2, sub-sections 1 and 2, number 1 to determine their plausibility and shall arrange for them to be completed where necessary.

(3) Subsequent to the examination pursuant to sub-section 2, the competent authority shall officially release the data to the German Institute for Medical Documentation and Information for inclusion in one of the databases named in Section 4, sub-section 1. With the release, the obligation of the competent authority to pass on data to the German Institute for Medical Documentation and Information pursuant to the Act on Medical Devices is deemed fulfilled. The competent authority shall inform the party who is liable to notify, pursuant to sub-section 1, of the data release.

Section 3a
Central collection system for notifications and applications in the case of clinical investigations and performance evaluation studies

(1) Section 3, sub-section 1 shall apply correspondingly to notifications and applications pursuant to Section 22, sub-section 1, sentence 1, Section 22a, sub-section 1, sentence 1, Section 22c, sub-sections 1 and 2, as well as Sections 23a and 24 of the Act on Medical Devices as well as pursuant to Section 7, sub-section 1 and Section 8, sub-section 2 of the Ordinance on the Clinical Investigation of Medical Devices, which are to be made to the competent higher federal authority and the competent ethics committee.

(2) The competent higher federal authority and the competent ethics committee shall enter their decisions on applications pursuant to sub-section 1, without delay, into the database provided for in Section 4, sub-section 1, number 3. With the entering of its decision in the database, the competent ethics committee will have fulfilled its obligation to inform pursuant to Section 22, sub-section 4, sentence 2 of the Act on Medical Devices.

(3) In an automated process, the authorities responsible for surveillance will be informed of decisions pursuant to sub-section 2, sentence 1.

Section 4
Medical devices databases

(1) The German Institute for Medical Documentation and Information (DIMDI) operates the following databases:

1. A database containing the contents of Annexes 1 and 2 to this Ordinance on:
   a) Notifications pursuant to Section 25 of the Act on Medical Devices, and
   b) Notifications pursuant to Section 30, sub-section 2 of the Act on Medical Devices,

2. A database containing the contents of Annex 3 to this Ordinance on certificates issued by notified bodies pursuant to Section 18, sub-section 3, no. 1 of the Act on Medical Devices,

3. A database containing the contents of Annex 4 to this Ordinance on clinical investigations and performance evaluation studies pursuant to Sections 20 to 24 of the Act on Medical Devices,

4. A database containing the contents of Annex 5 to this Ordinance on announcements regarding the classification of a medical device or on the differentiation of medical devices from other devices pursuant to Section 33, sub-section 2, no. 2 in conjunction with Section 13 of the Act on Medical Devices,

5. A database on the Medical Devices Vigilance System containing the data provided for in Section 29, sub-section 1, sentence 5 of the Act on Medical Devices; it shall contain information on notifications, as well as on the completion and the results of the risk evaluation in order to fulfil the obligations contained in Section 20, sub-section 1, sentence 1 and Section 22, sub-section 2, sentence 1 of the Medical Devices Safety Plan Ordinance of 24th June 2002 (FLG I, p. 2131) amended by Article 3 of the Law of 29th July 2009 (FLG I, p. 2326), as well as the announcements transmitted by the competent higher federal authorities pursuant to Section 21, sub-section 1, sentence 1 of the Medical Devices Safety Plan Ordinance or which they receive pursuant to Section 21, sub-section 2, sentence 1 of the Medical Devices Safety Plan Ordinance.

(2) The German Institute for Medical Documentation and Information may process and make available for use databases which are accessible both nationally and internationally and which contain information on medical devices.

Section 5
Use of the databases

(1) Alongside the Federal Ministry of Defence and the Federal Ministry of Health, the federal and Land authorities responsible for medical devices legislation, atomic energy legislation and metrology are entitled to retrieve data from the databases pursuant to Section 4, sub-section 1 free of charge in so far as necessary for the performance of their functions in enforcing the Act on Medical Devices.

(2) The notified bodies are entitled to use the database pursuant to Section 4, sub-section 1, no. 2 free of charge in connection with certificates which have been restricted, refused, suspended, reinstated, withdrawn or cancelled by the manufacturer.

(2a) The competent ethics committee pursuant to Section 22, sub-section 1 of the Act on Medical Devices and the ethics committees involved pursuant to Section 3, sub-section 1, sentence 4 of the Ordinance on the Clinical Investigation of Medical Devices are entitled to use the database pursuant to Section 4, sub-section 1, no. 3 free of charge in so far as necessary for the performance of their tasks in enforcing the Act on Medical Devices.

(3) The databases pursuant to Section 4, sub-section 1, no. 1, letter a and sub-section 2 are public. Notified bodies may use the databases pursuant to Section 4, sub-section 1, no. 1, letter a free of charge.

Section 6
Data protection and data security

In transmitting the data, state-of-the-art measures shall be taken to guarantee data protection and data security which ensure especially the confidentiality and integrity of the data; in cases where generally accessible networks are used, encoding procedures shall be employed.

Section 7
Data retention period

(1) Data stored in the database pursuant to Section 4, sub-section 1 shall remain available for a period of 20 years after the last modification of the data set in question. After this period has elapsed, the data shall be deleted.

Section 8
Right to disclosure

Section 19 of the Federal Data Protection Act shall be applied *mutatis mutandis* to legal persons.

Section 9 and Section 10
(deleted)