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Decree Nr. 2016-1716 of 13 December 2016 relating to the summary of the characteristics of the medical device

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Public concerned: manufacturers of medical devices and their authorized representatives, National Agency for the Safety of Medicines and Health Products.
Subject: content and procedures for the transmission of the summary of the characteristics of the product to be supplied by the medical device manufacturer or his authorized representative to ANSM.
Entry into force: the text shall enter into force on July 1st, 2017.
Notice: the decree specifies the content of the summary of the characteristics of the product to be supplied by the manufacturer of a medical device or his authorized representative to ANSM. The elements to be provided in this summary are elements relating to the identification of the device, its performance and its clinical evaluation; These elements belong to the CE marking file constituted in the context of the application for certification of conformity. The decree also provides for the transmission of this summary to ANSM.
References: The decree is taken for the application of article 147 of the law n ^{r} 2016-41 of January 26, 2016 of modernization of our health system. The provisions of the Public Health Code, as amended by this decree, can be consulted on the Légifrance website (http://www.legifrance.gouv.fr).

The Prime Minister,
On the report of the Minister of Social Affairs and Health,
Having regard to Council Directive 90/385 / EEC of 20 June 1990 and its modification on the approximation of the laws of the Member States relating to active implantable medical devices;
Having regard to Council Directive 93/42 / EEC of 14 June 1993 on medical devices, in particular Article 14b thereof;
Having regard to Directive 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations, together with notification 2016/378 / F;
Having regard to the Public Health Code, in particular Article L. 5211-4-1;
The Council of State (social section) heard,
Decree:

Article 1

After the article R. 5211-66 of the Public Health Code, an article R. 5211-66-1 is inserted as follows:

"Art. R. 5211-66-1.-I.- The medical devices subject to the transmission of the summary of their characteristics provided for in Article L. 5211-4-1 are, with exception to tailor-made devices:
"(1) Implantable medical devices;
"(2) Class III medical devices.
"This summary shall be sent by electronic means to the Director-General of the National Agency for the Safety of Medicines and Health Products when the medical device is put into service in the

national territory. Transmission is carried out for each commercial name, by the manufacturers, their authorized representative and the distributors who deliver the medical devices directly to the user.
"II.-The summary of the characteristics of the medical device comprises the following elements:
"1°. Identification of the medical device, the manufacturer and, where applicable, the authorized representative:
"a) The name or commercial name of the medical device, its class of risk and the applicable classification rules;
"b) The name, trade name or trademark of the manufacturer, the address of its head office and contact details; Where applicable, the same information concerning the authorized representative;
"c) The date of preparation of the summary of characteristics and its version number;
"2 ° Elements on the use of the medical device:
"a) The destination of the medical device including medical indications, contraindications and the target population;
"b) The place of the medical device in the diagnostic or therapeutic strategy;
"c) The users concerned and the training required for them;
"d) Information on residual risks, any adverse reactions and any precautions for use;
"(3° A description of the medical device, including:
"a) The operating principle of the medical device;
"b) Where applicable, a reference to the previous model and a description of the modifications made;
"c) A description of accessories, other medical devices or products or substances which are not medical devices, intended to be used in combination with the medical device;
"d) A description or list of the various presentations or variants of the medical device that will be available;
'e) A reference to the standards used by the manufacturer and, where appropriate, the authorized representative;
"4 ° Elements on clinical evaluation and follow-up after placing on the market:
"a) A summary of the results of the clinical assessment referred to in Article R. 5211-36-1;
"b) Information relating to the systematic review of data acquired on the medical device provided for in Article R. 5211-39.
'Any significant modification of an element mentioned in II of this Article shall be notified without delay to the Agency by the persons mentioned in the last paragraph of I.''

Article 2
The provisions of this Decree shall enter into force on July 1st of 2017.

Article 3
The Minister of Social Affairs and Health is responsible for the implementation of this decree, which will be published in the Official Journal of the French Republic.

Dated this 13th day of December, 2016.

Bernard Cazeneuve

By the Prime Minister:
The Minister of Social Affairs and Health,

Marisol Touraine