New Medical Device Regulation EU 2017/745 (MDR)

Dear customers, dear partners,

ISIS, as many other manufacturers and suppliers of medical devices, will be subject to the new regulation on **M**edical **D**evices EU 2017/745, which will replace the old directive (93/42/EEC) and will come into force on May 26th, 2020.

On this date, this new regulation will replace the old directive (93/42/CEE). ISIS solutions are **class I medical devises** in accordance to the old directive.

The new regulations reinforce the prerequisites necessary for CE marking, and in particular, impose a class reassessment for each medical device according to precise criteria and depending on the intended use and the environment of the device.

Thus, after analysis and evaluation carried out by a competent third party, and on the basis of the new classification rules for a medical device, it is proven that the systems and devices marketed by ISIS will not change class and **they therefore always fall under Class I** (Rules 1 and 13 of the MDR).

However, the new regulations imply to take into account new reinforced requirements, directly involving the ISIS teams, who are already strongly mobilized, and who are implementing an action plan to comply with these regulations, including here are the highlights:

- ✓ **Updating** the Quality Management System by integrating the requirements of the regulations and **improving the QMS**.
- ✓ **Creation and improvement** of post-market monitoring processes.
- ✓ **Updating of technical files** incorporating the new requirements.
- ✓ **Integration** of the new **transparency** requirements with the **EUDAMED*** database.
- ✓ **Modification** of product **marking and traceability** with the **creation of IUD code ****

** EUDAMED stands for European Databank on Medical Devices. It is a digital platform for manufacturers.*

*** UDI stands for Unique Device Identifier. Under the responsibility of the manufacturer, an UDI code must be affixed to the device for marketing. The UDI is registered by the manufacturer or the distributor in EUDAMED.*

Our customers, as well as business partners (distributors, agents and importers), must also comply with this new regulation, with, for example in terms of traceability, one of the new elements of the MDR (Medical Devices Regulation) which imposes the registration of product (s) in the EUDAMED database and designation of a person responsible for ensuring compliance with the regulation.

ISIS thanks you for your confidence and is at your disposal if you wish more information, and to assist you in your respective steps.

Saint-Ismier, 10th April 2020

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Xavier Priquel, *Chief Executive Officer*

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Clémentine Sciascia, *Quality and Regulatory Affairs Manager*