Medical Device Regulation (MDR) Quality Commitments for Insightec Third Party Sellers

Consistent with your commitment, as our third party seller, to follow our reasonable directions and requirements in relation to your performance under our agreement, if your performance implicates the MDR you will comply with MDR generally, and the following list of MDR Economic Operators obligations and requirements specifically ("**MDR Quality Commitments**").

1. As required under MDR Article 31:
    a. You will update data described below in the electronic system (EUDAMED), within one week of any change occurring in relation to any of the following data: type of economic operator (manufacturer, authorized representative, or importer); name, address and contact details of the economic operator; where submission of information to the electronic system (EUDAMED) is carried out by another person on behalf of any economic operator (manufacturer, authorized representative, or importer), the name, address and contact details of that person; and the name address and contact details of the person or persons responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. Or, information relating to the device:
        1. Basic UDI-DI,
        2. Type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body and the link to the information that appears on the certificate,
        3. Member State in which the device is to or has been placed on the market in the Union,
        4. in the case of class IIa, class IIb or class III devices: Member States where the device is or is to be made available,
        5. risk class of the device,
        6. presence of a substance which, if used separately, may be considered a medicinal product and name of that substance,
        7. where applicable, the single identification number of the clinical investigation or investigations conducted in relation to the device or a link to the clinical investigation registration in the electronic system on clinical investigations,
        8. in the case of devices designed and manufactured by another legal or natural person as referred in Article 10(15), the name, address and contact details of that legal or natural person, 5.5.2017 L 117/115 Official Journal of the European Union EN
        9. status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated).
    b. Not later than one year after your submission of the data elements noted in the bullet point above to the electronic system (EUDAMED), and every second year thereafter, you will confirm the accuracy of such data. In the event of a failure to do so within six months of those deadlines any EU Member state may take appropriate corrective measures within its territory until you comply.

2. Translation – you will ensure that the applicable regulatory requirements per the EU declaration of conformity (which you will translate) are delivered to Insightec.
3. Trainings – you will attend, and will ensure your customers who gain access to our products attend, specified trainings as we may require, such as trainings regarding performance and safe use of our System.
4. Regulatory requirements – if you perform your obligations under our agreement within the EU, you will comply with the specific requirements set forth in MDR (EU) 2017/745 Article 14 related to placing our products in the market, such as vigilance reporting to competent authorities and us.

   Before making our product available on the market, you will verify that all applicable regulatory requirements are met, including:

   a. you will ensure that the product has been CE marked and the EU declaration of conformity of the product has been drawn up (as required in the MDR)

   b. you will ensure the product is accompanied by additional information provided by us

   c. you will ensure that the importer (if any) has indicated on the product, the packaging or in a document accompanying the product, the product name, registered trade name or registered trade mark, your registered place of business, and the address at which you can be contacted

   d. where applicable, you will confirm we have assigned an unique device identifier (UDI), and notify us promptly if not

   e. you will keep a register of Post Market Surveillance (PMS) information, complaints, non-conforming Insightec products and of recalls and withdrawals of the products, and keep us and, where available, the authorized representative and the importer, informed of such monitoring and provide us and them with any information upon request.

   f. you will not make the product available on the market if you believe, or have a reason to believe, that a product is not in conformity with the requirements of MDR 2017/745, and inform us and, where applicable, our authorized representative, and the importer, and work with us and them to remedy the non-conformity.

   g. you will immediately inform us and the competent authority of the Member State in which the product had been available, if you believe, or have a reason to believe, that a product presents a serious risk or is a falsified product, giving details, in particular, of the non-compliance and of any corrective action taken.

   h. you will cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by products made available on the market by you, consistent with MDR Article 14.

   i. you will, upon request by a competent authority, provide it with all the information and documentation that is at your disposal and is necessary to demonstrate the conformity of a product, requesting any legally permissible confidentiality protections.

5. You will inform us of any changes in medical device regulations in the applicable territory that would impact performance of our agreement or these MDR Quality Commitments.

6. You will immediately inform us and, when applicable, our authorized representative, of any customer complaint, any PMS plan information described in Section 1 of Annex 3 in the MDR, or reports from healthcare professionals, patients or users about suspected incidents related to a product that you have made available, perform your regulatory duties, assist us in case of recall and keep a list of customers gaining access to our products through you (including the location and serial number of the supplied product).

7. You will comply with relevant Confidential Health Information regulations and rules. If, in working with our products, you receive or are exposed to health information of patients, you will maintain the confidentiality of the same and not use except to send any required information to authorized Insightec's clinical department personnel only.

These MDR Quality Commitments do not modify our agreement, except in the event there's a conflict between these MDR Quality Commitments and our agreement which make compliance with both not feasible, you will notify us of the same and, unless we notify you otherwise, the specific requirements and obligations in these Quality Commitments will control over the conflicting agreement provisions.