1. SCOPE

Regulation (EU) 2017/745 on medical devices replaced Directive (EU) 93/42/EEC for medical devices on 26 May 2017 and the transitional period for implementation ended on 26 May 2021. EU MDR imposes additional obligations on distributors of medicals devices that must be fulfilled to maintain compliance with the Applicable Law.

These Terms and Conditions define the requirements for **Distributors** of medical device products supplied in accordance with EU MDR and are considered to be accepted for all products procured from the date of issuing this document (22 MAR 2022).

2. DEFINITIONS

2.1. Terms and Conditions: means the Terms and Conditions within this document as amended, and includes all Annexes thereto.

2.2. Applicable Law(s): means all laws, ordinances, rules, and regulations of any governmental or regulatory authority that apply to the parties under these Terms and Conditions, including without limitation of;

2.2.1. REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

2.3. Applicable Standard(s): ISO 13485:2016 or ISO 9001:2015.

2.4. Authorised Representative: means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under the applicable regulation.

2.5. Business Day(s): any day other than a Saturday and Sunday.

2.6. Commencement Date: the date of issuing these terms and conditions.

2.7. Confidential Information: information in whatever form (including in written, oral, visual or electronic form or on any magnetic or optical disk or memory and wherever located) relating to the business, customers, products, affairs and finances of Sanofi for the time being confidential to Sanofi and trade secrets including technical data and know-how relating to Sanofi’s business or any of its products, suppliers, customers, agents, importers, shareholders, management or business contacts, and including information that Distributor creates, develops, receives or obtains in connection with this Engagement, whether or not such information (if in anything other than oral form) is marked confidential, and including the following:

2.7.1. Any information relating to the trading position of Sanofi or its customers and suppliers, including in particular names and contact details of suppliers, partners, clients or customers;

2.7.2. Any information relating to the business, products, affairs and finances of Sanofi and its customers;

2.7.3. Any information or data relating to the design, specification or performance of Sanofi`s products and tools;

2.7.4. Any information relating to the development of products or Inventions of Sanofi or any employee of Sanofi;

2.7.5. Any medical or personal information about patients or users of the products of Sanofi;

2.7.6. Any information relating to the marketing plans, business development or structure of Sanofi and its customers; and

2.7.7. Any document or item marked as confidential.

2.8. Complaint: written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organisation's control or related to a service that affects the performance of such medical devices.

2.9. Distributor: means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.

2.10. Economic Operator: means a manufacturer, an Authorised Representative, an importer, a distributor or the person referred to in EU MDR, Article 22(1), systems and procedure pack assembler, and 22(3), sterilizer of systems and procedure packs

2.11. EU: means the European Union.

2.12. EU MDR 2017/745: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

2.13. Importer: means any natural or legal person established within the European Union that places a device from a third country on the Union Market.

2.14. Intellectual Property: means patents, rights to apply for patents, trademarks, trade names, service marks, domain names, copyrights and all applications and registration of such worldwide, schematics, industrial models, inventions, know-how, trade secrets, computer software programs, and other intangible proprietary information.

2.15. ISO 13485:2016: International standard – Medical devices – Quality management systems – Requirements for regulatory purposes.

2.16. Label: means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices.

2.17. Making available on the market: means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.

2.18. Manufacturer: means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

2.19. Medical Device: shall have the meaning as defined by the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, ARTICLE 2 as applicable.

2.20. Notified Body: means a conformity assessment body designated in accordance with Applicable Law.

2.21. Placing on the market: means the first making available of a device, other than an investigational device, on the Union market.

2.22. Product(s): means the item, portion and/or component parts made available by Distributor further set forth in the Annex I, including the labelling, instructions for use, where applicable, and packaging. Product refers to medical devices according to EU MDR 2017/745.

2.23. Quality Management System (QMS): A formalised system that documents the structure, responsibilities and procedures required to achieve effective quality management.

2.24. Territory: European Union (also referred to as Union).

2.25. Trademark: means a name or symbol on a product that shows it was made by a particular company, and that it cannot be used by other companies without permission.

2.26. Union: The Union is comprised of the EU plus all countries that have a mutual recognition scheme with the EU for devices.

2.27. Unique Device Identifier (UDI): means a series of numeric or alphanumeric characters that are created through internationally accepted Product identification and coding standards and that allow unambiguous identification of specific Products on the Territory.

3. OBLIGATIONS OF SANOFI

3.1. **Sanofi** shall agree to adhere to the requirements of Applicable Law(s).

3.2. **Sanofi** shall ensure that processes and procedures are in place to implement the principles and actions necessary to achieve compliance with the provisions of these Terms and Conditions and Applicable Law.

3.3. **Sanofi** shall only supply **Distributor** with Product that they deem to be in compliance with Applicable Law.

3.4. **Sanofi** shall co-operate with **Distributor** to achieve an appropriate level of traceability of Product.

3.5. **Sanofi** shall provide **Distributor** with the required information to enable the relevant verification activities to be completed.

3.6. **Sanofi** shall inform **Distributor** of any relevant changes to Product that are received from the Manufacturer.

3.7. **Sanofi** shall communicate any relevant information received from **Distributor** to Economic Operators in the Supply Chain where applicable (Manufacturer, Importer and Authorised Representative).

4. OBLIGATIONS OF DISTRIBUTORS

4.1. **Distributor** shall agree to adhere to the requirements of Applicable Law(s).

4.2. **Distributor** shall ensure that processes and procedures are in place to implement the principles and actions necessary to achieve compliance with the provisions of these Terms and Conditions and Applicable Law.

4.3. **Distributor** shall co-operate with **Sanofi** to achieve an appropriate level of traceability of Product.

4.4. **Distributor** shall be able to identify the following to the competent authority, for a period of 10 (ten) years (or a period of 15 (fifteen) years for Class III implantable devices):

4.4.1. any economic operator to whom they have directly supplied a device;

4.4.2. any economic operator who has directly supplied them with a device;

4.4.3. any health institution or healthcare professional to which they have directly supplied a device.

4.5. To make Product available on the Territory, **Distributor** shall verify that:

4.5.1. The Product has been CE marked and that the EU declaration of conformity of the Product has been drawn up;

4.5.2. The device is accompanied by the information to be supplied by the manufacture in accordance with Applicable Law (labelling and instructions for use where applicable).

4.5.3. For imported devices, the importer has complied with the requirements set out in Applicable Law.

4.5.4. Where applicable, a UDI has been assigned by the Manufacturer;

4.6. **Distributor** shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to Class III implantable devices according to EU MDR.

4.6.1. **Distributor** shall assume the obligations incumbent on Manufacturer in accordance with Applicable Law if it carries out any activities stated under Article 16 of EU MDR. Under these circumstances, **Distributor** shall notify **Sanofi** in writing, and if the activities are permitted by the manufacturer, amend these Terms & Conditions accordingly. Under the terms and conditions defined here, **Distributor** shall not:

4.6.2. make available on the market a device under its name, registered trade name or registered trade mark;

4.6.3. change the intended purpose of a device already placed on the market or put into service;

4.6.4. modify a device already placed on the market or put into service in such a way that affects compliance with Applicable Law;

4.6.5. translate the information supplied by the manufacturer or of further information which is necessary in order to market the device in the relevant Member State;

4.6.6. change the outer packaging of a device already placed on the market, including a change of pack size.

4.7. When **Distributor** considers or has reason to believe that a Product is not in conformity with the requirements of Applicable Law, it must not make the Product available on the market until it has been brought into conformity and shall inform

Sanofi who will in turn inform the Manufacturer and, where applicable, the Manufacturer's Authorised Representative, and the Importer.

4.8. Where the **Distributor** considers or has reason to believe that the Product presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which the **Distributor** is established.

4.9. **Distributor** shall ensure that, while Product is under their responsibility, storage or transport conditions comply with the conditions set by the Manufacturer and damage, deterioration, contamination o other adverse effects do not occur during the storage, handling and transportation of the Product.

4.10. **Distributor** shall ensure that no obsolete, rejected, expired or deteriorated Product are distributed.

4.11. **Distributor** shall have controls in place to allow for physical and/or electronic quarantine of Product, as necessary.

4.12. **Distributor** who considers or have reason to believe that Product which they have made available on the Territory is not in conformity with Applicable Law must immediately inform **Sanofi** who will in turn immediately inform the Manufacturer and, where applicable, the Manufacturer's Authorised Representative and the importer.

4.13. **Distributor** shall co-operate with **Sanofi**, Manufacturer and, where applicable, the Manufacturer's Authorised Representative, and the Importer, and with competent authorities to ensure that the necessary corrective action to bring that Product into conformity, to withdraw or recall it is taken. Where the Product presents a serious risk, **Distributor** shall immediately inform the competent authorities of the Member States in which they made the Product available, giving details, in particular, of the non-compliance and of any corrective action taken.

4.14. Information about Complaints or reports from healthcare professionals, patients or users about suspected incidents related to a Product which **Distributor** has made available on the Territory, that are received by **Distributor** must immediately be forwarded to **Sanofi** who in turn will immediately inform Manufacturer and, where applicable, the Manufacturer's Authorised Representative, and the importer.

4.15. **Distributor** shall keep a register of Complaints, of non-conforming Products and of recalls and withdrawals, and keep **Sanofi** informed of such monitoring and provide **Sanofi** with any information upon their request.

4.16. **Distributor** shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device. **Distributor** shall be considered to have fulfilled this obligation when **Sanofi**, Manufacturer or, where applicable, the Manufacturer's Authorised Representative for the device in question provides the required information.

4.17. **Distributor** shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by Product which they have made available on the Territory. **Distributor**, upon request by a competent authority, will provide samples of the Product free of charge or, where that is impracticable, grant access to the Product.

4.18. **Distributor** shall put Terms and Conditions and/or Agreements in place with any Economic Operators within its own supply chain and adhere to all terms set out within these Terms and Conditions and Applicable Law.

4.19. **Distributor** shall not (except in the proper course of its duties), either during the Engagement or at any time after the termination date of this Agreement, use for its own benefit or the benefit of others, divulge or communicate to any person, firm or organization, any of the trade secrets or other Confidential Information, technical or commercial information of **Distributor** and other Economic Operators related to business, organization, accounts, analysis or other affairs of Economic Operators or its customers which it may have received or obtained during the Engagement.