Note: *Articles (Art.) quoted in italics refer to Regulation (EU) 2017/745. Terms in quotation marks (at their 1st appearance) have the meaning given to them by this regulation. The latest updates are in blue.*

These Regulatory General Conditions apply to Customers of the company HEMODIA, 'distributors' of 'medical devices (MD)' that are 'made available on the market' in the European Union. They are an integral part of the HEMODIA's Terms and Conditions of Sale with which they form an indivisible and inseparable whole. Acceptance of the Terms and Conditions of Sale by the Customer implies acceptance of the Regulatory General Conditions, which shall apply to any order of medical device (MD) from HEMODIA.

The distributor acts, within the framework of its activities and when making a MD available, with due diligence in order to fulfil the applicable requirements (*Art. 14.1*).

The distributor:

- Ensures that its sub-distributors and affiliates comply with these Regulatory General Conditions.
- Distributes MD supplied by HEMODIA only in the European Union.
- If applicable, comply with national provision concerning the registration of distributor (*Art. 30.2*).
- Does not make any change to the MD supplied (including its 'label' or 'instructions for use').
- Accepts audits by HEMODIA or its notified body.
- Before being made available on the market, checks that the following conditions are met (*Art. 14.2*):
  a) The MD bears the CE mark and the EU declaration of conformity has been drawn up.
  b) The MD is accompanied by a label and, where applicable, an instruction for use, in the language of the Member State in which the MD is made available.
  c) Where applicable, the name and address of the 'importer' can be found on the MD, on its packaging or in an accompanying document.
  d) The 'manufacturer' has assigned, where applicable, a 'unique device identifier (UDI)' to the MD.

  For points a, b and d, it is possible to apply a sampling method that is representative of the MD supplied.
- Informs the manufacturer and, where applicable, the 'authorised representative' and the importer if it considers that a MD is not compliant and does not make it available on the market until it has been brought into compliance. It also informs the competent authority of the Member State in which it is established, in the event of a 'serious risk' or 'falsified device'.
- While the MD is under its responsibility, ensures that storage and transport conditions comply with the conditions defined by the manufacturer (*Art. 14.3*).
- After it has been made available on the market, if it considers that a MD does not comply with Regulation (EU) 2017/745: Informs immediately the manufacturer and, where applicable, the authorised representative and the importer; Cooperates with the manufacturer, and where appropriate with the authorised representative and the importer, as well as with the competent authorities, to ensure that the necessary corrective actions are taken: bringing into conformity, 'withdrawal' or 'recall' of the MD; Also immediately informs the competent authorities of the Member States in which the MD has been made available, in the event of a serious risk (*Art. 14.4*).
- Immediately forwards to the manufacturer and, where applicable, to the authorized representative and to the importer, any complaints or report from healthcare professionals, patients or users related to or possibly related to a MD it has made available on the market (*Art. 14.5*).
- Keeps a register of complaints, non-compliant MD, 'recalls' and 'withdrawals'. Provides any information requested by the manufacturer and, where applicable, the authorised representative and the importer (*Art. 14.5*).
- Cooperates with manufacturers or authorised representatives to achieve an appropriate level of traceability for MD. Is able to identify, for a period of 10 years (15 years for implantable MD), who supplied him with a MD and to whom he supplied it (*Art. 25*).
- Cooperates with the competent authorities, provides samples free of charge or gives access to the MD (*Art. 14.6, 93.3 et 94*).
- Takes the appropriate 'corrective action' and ensures that they are implemented without delay, when a competent authority identifies an 'unacceptable risk' for health or safety (*Art. 95.1 et 95.3*).
- Terminates the non-compliance within an appropriate period, in the case of non-compliance that does not present an unacceptable risk to health or safety (*Art. 97.1*).
- Does not use information that could mislead the user or the patient with regard to the intended purpose, safety and performance of the MD (*Art. 7*).
- Is bound by an obligation of confidentiality regarding: Personal data; confidential information of a commercial nature and trade secret, including intellectual property rights, unless the public interest justifies disclosure; The implementation of the Regulation (EU) 2017/745, in particular with regard to inspections, investigations or audits (*Art. 109*).

HEMODIA SAS Privacy Policy: https://www.hemodia.com/en/cookies-and-privacy

HEMODIA - 85 Rue du Chêne Vert - 31670 Labège - FRANCE
Tel: +33 (0)5 61 00 71 81 - Fax: +33 (0)5 61 00 47 40 - hemodia@hemodia.com - www.hemodia.com
S.A.S au capital de 4 000 000 € - RCS Toulouse : B 331 772 160 – SIRET : 331 772 160 00049 – TVA : FR 74 331 772 160 – NAF : 3250A