

## United Kingdom's withdrawal (Brexit) from European Union – Consequences for the distribution of your medical devices/cosmetic products

**The European commission issued a notice on 22 January 2018  
(European Commission, NOTICE TO STAKEHOLDERS WITHDRAWAL OF THE UNITED  
KINGDOM AND EU RULES IN THE FIELD OF INDUSTRIAL PRODUCTS, Brussels, 22  
January 2018)**

The notice discusses the preparation of economic operators e.g. manufactures for the United Kingdom's withdrawal.

According to the current withdrawal notification, the United Kingdom will withdraw from European Union from 30 March 2019, 00:00 (CET) ("the withdrawal date"). The United Kingdom will then become a third country to European Union and Union law will cease to apply to the United Kingdom from that date on.

### **1. European Authorized Representative/Responsible Person located in UK not accepted anymore**

In the Medical Device Directive 93/42/EEC, Medical Device Regulation 2017/745, and Cosmetic Regulation 1223/2009, the entity act as "European Authorized Representative"/"Responsible Person" shall be established in the European Union. Authorized Representatives or Responsible Persons established in the United Kingdom will not, as from the withdrawal date, be recognized as Authorized Representatives or Responsible Persons for the purposes of the applicable Union product legislation. Therefore, manufacturers are advised to take the necessary steps to ensure that, as from the withdrawal date, their designated Authorized Representatives or Responsible

Persons are established in the EU member states.

### **2. Notified Body located in UK not accepted as EU Notified Body anymore**

Union product legislation requires Notified Bodies to be established in a member state and be designated by a member state notifying authority for performing the conformity assessment tasks set out in the relevant act of Union product legislation. Therefore, as from the withdrawal date, UK Notified Bodies will lose their status as EU Notified Bodies. As such, they will no longer be in the position to perform conformity assessment tasks as from the withdrawal date, unless the UK withdrawal agreement establishes exceptions.

### **3. UK manufacturer cannot act as importer anymore**

According to European Union product legislation, the importer is the economic operator established in the Union who places a product from a third country on the Union market. As from the withdrawal date, a manufacturer or importer established in the United Kingdom will no longer be considered as an economic operator established in the Union.

**For more detailed information, please do not hesitate to contact us!**