ANNEX 1
to the Rules

F.1 - Notification form for the introduction of medical devices on the market

To,

THE MINISTRY OF HEALTH

THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES OF ROMANIA

<table>
<tr><td colspan="2">1. Identification data of the notification</td></tr>
<tr><td colspan="2">Please specify whether this is the first notification or a change:

☐ first notification ☐ change

☐ suspension of the introduction on the market ☐ termination of the introduction on the market</td></tr>
<tr><td colspan="2">If it is a change or suspension/termination, please specify the previously assigned number:</td></tr>
<tr><td colspan="2">Number of pages of the notification:</td></tr>
<tr><td colspan="2">Status of the organisation making this notification:</td></tr>
<tr><td>☐ class I medical devices manufacturer

☐ class II medical devices manufacturer

☐ class IIb medical devices manufacturer

☐ class III medical devices manufacturer

☐ manufacturer of systems and procedure packs</td><td>Authorised representative of a:

☐ class I medical devices manufacturer

☐ class IIa medical devices manufacturer

☐ class IIb medical devices manufacturer

☐ class III medical devices manufacturer</td></tr>
</table>

☐ manufacturer of active implantable medical devices	☐ manufacturer of systems and procedure packs ☐ manufacturer of active implantable medical devices
2. Manufacturer identification data	
Manufacturer’s full name:	
Manufacturer’s abbreviated name:	
Address of the manufacturer's registered office:	
Country:	SRN:
Postal code:	Sector/county:
City/town:	Street no.:
Telephone number:	Fax number:
E-mail address:	Contact person:
Person responsible for compliance with regulations specific to the field of medical devices:	
3. Authorised representative’s identification data	
Authorised representative’s full name:	
Authorised representative’s abbreviated name:	
Address of the authorised representative's registered office:	
Country:	SRN:
Postal code:	Sector/county:
City/town:	Street no.:
Telephone number:	Fax number:
E-mail address:	Contact person:
Person responsible for compliance with regulations specific to the field of medical devices:	
4. Medical device’s identification data	
Medical device’s full name:	
Class/type of the medical device: ☐ class I medical device ☐ class Is medical device ☐ class Im medical device ☐ class IIa medical device ☐ class IIb medical device ☐ class III medical device	

☐ systems and procedure packs ☐ active implantable medical device
Generic category of the medical device and/or brief description of the device and its intended purpose:
5. Attached documents
☐ copy certified for compliance of the registration certificate or other official document/normative act certifying the establishment of the applicant unit and the ascertaining certificate issued by the trade register office from which the object of the company's activity results, for the applicant units which have the obligation to register at the trade register office
☐ declaration of compliance issued by the manufacturer in accordance with the applicable legislation
☐ instructions for use of the medical device
☐ medical device label
☐ copy of the certificate of compliance issued by a notified body (as appropriate, depending on the type of medical device)
☐ the document by which the manufacturer appoints you as an authorised representative in line with Article 11 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

The information provided in this notification is correct and the medical devices identified in section 4 meet the applicable requirements set out in Regulation (EU) 2017/745 of the European Parliament and of the Council.

Last name, first name and function

Signature and stamp