

MD REGULATORY DIGEST

FOCUS ON

'MAKING AVAILABLE'

Here is a clarification of the terms 'making available on the market', 'placing on the market' and 'putting into service', defined in Art. 2.

According to the MDR,

'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;

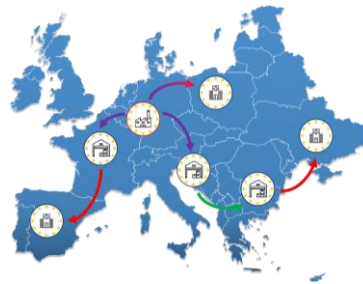
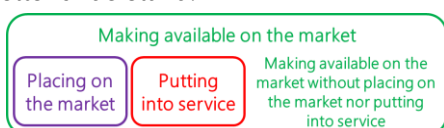
'Placing on the market' means the first making available of a device, other than an investigational device, on the Union market;

'Putting into service' means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

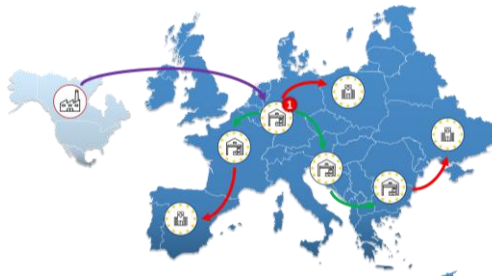
This means that by making a device available on the market you can either:

- Place it on the market,
- Put it into service,
- Or make it available without placing it on the market nor putting it into service

Here are some diagrams to help you better understand:



Here the manufacturer is established **within the EU**. The devices it supplies to any other entity is placed on the market. Then it is put into service when it reaches the final user (a hospital for example).



In this case, the manufacturer is located **outside the EU**. The first receiver of its device is the importer, who places it on the market. Then the device is made available on the market, and is finally put into service when it reaches the final user.

Legend:



LATEST NEWS



European Commission:
State-of-play of joint assessments of Notified Bodies published.

Main information below

To date:

38 MDR & 9 IVDR
Applications sent to
SANTE/F (Scope coverage:
overall, the entirety of MD
and IVD codes)

27 MDR & 6 IVDR
Preliminary assessment
reports received

1 JAT to be appointed

11 CAPA plans received
✓ 7 JAT opinions issued
✓ 1 CAPA plans
undergoing official
translation
✓ 3 JAT opinions under
preparation

2 Designating authorities'
final reports received
✓ 2 JAT opinion issued
✓ 1 MDCG
recommendation

23/04/2019

<https://ec.europa.eu/docs/en/gov/documents/35043>