



Technical expert seminar (EU27) on medical devices in relation to the withdrawal of the United Kingdom from the EU

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Health Technology and Cosmetics
DG Internal Market, Industry, Entrepreneurship and SMEs

UK's withdrawal from the EU

As of **30 March 2019, 00:00h** (CET), in the absence of a ratified withdrawal agreement:

- UK becomes a third country
- MD coming from the UK to be considered as **import**
- **MD placed on the UK market prior to the withdrawal date, but made available (e.g. sold) on the EU27 market as of the withdrawal date => placing on the Union (EU27) market occurs as of the withdrawal date**
- UK conformity assessment bodies **no longer 'Notified Bodies'** in NANDO

Placing on the EU27 market

Art.1(2)(h) MDD

Art. 2 MDR, points 27-28

- **'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;

Placing on the EU27 market

Placing on the market:

- relates to each **individual unit**, even if manufactured in series
- first making available on the EU27 market
 - does **not** require physical **delivery** of the device
 - **but** requires the **manufacturing** stage to be **completed**
 - for imported MD: section 2.4 of the Blue Guide:

<http://ec.europa.eu/DocsRoom/documents/18027>

(in particular placing on the market vs. release for free circulation by customs)



Authorised Representative - appointment

- UK manufacturer => requires an EU27 AR
- Can UK manufacturer appoint EU27 AR prior to the withdrawal date?
The question arises because until the withdrawal date UK is EU28 MS!
=> The appointment of AR can take place before the withdrawal date, but should take effect as of the withdrawal date ('conditional appointment')
- UK AR appointed by 3rd country manufacturer for the EU => requires re-location to EU27 / appointment of a new AR in EU27



Authorised Representative - information update

- Update of the **Declaration of Conformity** and the **certificate**, if AR has been indicated in those documents
- Update of the **competent authority** of MS where AR has a registered place of business
 - MDD Article 14(1) and (2) (Class I + custom made)
 - AIMD Article 10a(2) the second subparagraph (custom made)
 - IVDD Article 10(3)
- Update in **Eudamed** (Eudamed Decision C(2010) 2363), where appropriate

Authorised Representative

- information supplied with the device

- MD placed on the EU27 market **prior** to the withdrawal date => **no changes**
- MD placed on the EU27 market ***as of*** the withdrawal date:
 - MDD => EU27 AR needs to be indicated on the label, or the outer packaging, or instructions for use (Annex I ER 13(3)(a))
 - AIMD => EU27 AR needs to be indicated on the sales packaging (Annex I ER 14(2))
 - IVDD => EU27 AR needs to be indicated on the label, or the outer packaging, or instructions for use (Annex I ER 8(4)(a))

Importers / distributors

- Current EU27 distributors become EU27 **importers** for devices they place on EU27 market that they have purchased from a UK manufacturer
- The same applies for devices imported from third countries and first placed on the UK market

Transfer of certificates and change of NB number

- As of withdrawal date, manufacturer must have a certificate of an EU27 NB to place devices on EU27 market
 - **transfer of the existing certificate** from UK NB to EU27 NBor
 - a **new certificate** from an EU27 NB
- ***CE marking - NB identification number***
 - devices placed on the EU27 market or manufactured ***prior*** to the certificate transfer => **no change, provided that the product documentation is in order**
 - devices manufactured **after** the certificate transfer => **change**

Competent authorities' advice to the operators (1/2)

Competent authorities to raise awareness among national stakeholders about regulatory consequences for medical devices placed on the EU27 market prior to or as of the withdrawal date

- **Devices manufactured in the UK or imported into the UK from third countries, with an intention of further distribution in EU27:**

- **Economic operators to:**

- ❑ Review the status of key actors in the regulatory chain to see if changes are needed (e.g. appointment of EU27 AR; EU27 distributor becomes an importer)
- ❑ Update competent authorities where needed (e.g. any national databases)
- ❑ For individual items/batches, keep documentation which indicates the date of their placing on EU27 market

Competent authorities' advice to the operators (2/2)

- **Devices certified by UK NBs:**

- **Economic operators to:**

- ❑ Transfer the certificates to EU27 NB or seek new certificates from EU27 NB
- ❑ Update product documentation (Declaration of Conformity and NB Certificate) with new NB details, change NB number on product manufactured after certificate transfer or new certificate issued
- ❑ For individual items/batches manufactured with a UK NB number on them, keep documentation which indicates the date of manufacture

Re-location of UK Notified Bodies to EU27

- **NB 0086 – BSI Assurance UK Ltd:** 2017/745, 90/385, 93/42, 98/79
- **NB 0088 - LLOYD'S REGISTER QUALITY ASSURANCE LTD:** 93/42, 98/79
- **NB 0120 - SGS United Kingdom Limited:** 93/42, 98/79
- **NB 0473 – AMTAC CERTIFICATION SERVICES LTD:** withdrawn (previously: 93/42, 98/79)
- **NB 0843 – UL INTERNATIONAL (UK) LTD:** 93/42 (re-designation under Reg 920/2013 not finalised), 98/79
 - **Following the withdrawal date, UK NBs will lose their status and will be removed from NANDO**
 - **Relocation of activities to EU27 as an option**



Guidance

- Brexit negotiations and preparedness - general website

https://ec.europa.eu/info/brexit_en

- Brexit – general website with guidance to stakeholders on impact in the field of industrial products

https://ec.europa.eu/growth/content/brexit-%E2%80%93-guidance-stakeholders-impact-field-industrial-products_en

- Notice to stakeholders - 22/1/2018 – Withdrawal of the UK and EU rules in the field of industrial products

https://ec.europa.eu/info/sites/info/files/file_import/industrial_products_en_1.pdf

- Industrial products – Questions and Answers – 1/2/2019

https://ec.europa.eu/info/sites/info/files/qa_brexit_industrial_products_en.pdf