TÜV®

TÜV NORD

# BREXIT and the impact to Medical Devices Regulations

**TÜV NORD** CERT GmbH
Projectmanagement Medical
Langemarckstraße 20
45141 Essen
Germany
Tel.: +49 (0)201/825-2236
medical@tuev-nord.de

On 2021-01-01 the United Kingdom (UK) left the European Union.

At the same date the existing and future European Regulations are no longer binding for the four countries forming the UK (England, Scotland, Wales, Northern Ireland).

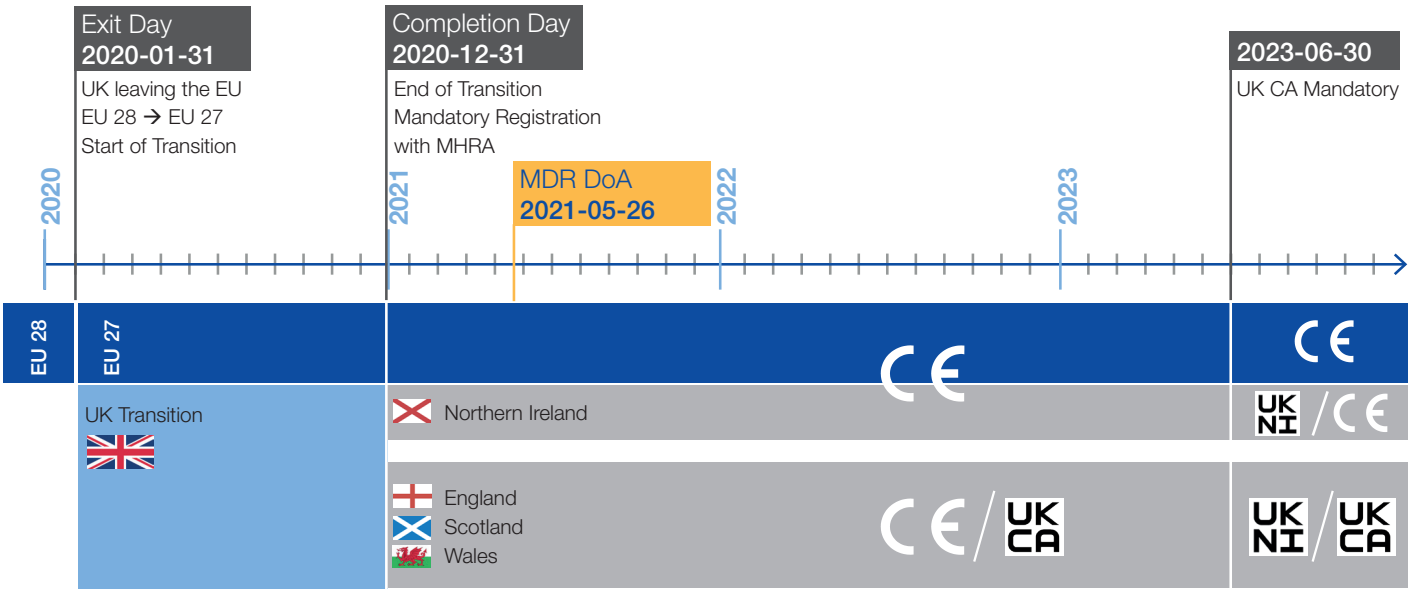
Whereas Great Britain (GB) with its countries England, Scotland and Wales will – after a short transition period – refrain from accepting the CE-marking, Northern Ireland will continue to accept products being placed on the market with the CE-marking for medical devices. In addition Northern Ireland is introducing the UK NI mark.

The transition period accepting the CE-marking for medical devices will end 2023-06-30.

After having left the EU the valid legislation for medical devices for Great Britain is “Medical Device Regulations 2002” published as SI 2002 No. 618 (not to confuse with the “new EU MDR”).

The “Medical Devices Regulations 2002” as applied in Great Britain originated as the national transposition of the former three EU-Directives on medical devices, will continue to be applicable after the Brexit (2021-01-01) and even after the “date of application” (DoA) for the European MDR (EU)2017/745 (2021-05-26).

## BREXIT TIMELINES AND PRODUCT MARKING



# BREXIT and the impact to Medical Devices Regulations

The competent authority administering and enforcing the law for Great Britain is the MHRA (Medicines & Healthcare products Regulatory Agency).

As the European directives and regulations are no longer applied in Great Britain the European Conformity mark “CE” needs to be replaced by the new “UK CA” mark. This mark will identify products that comply with the current legislation in Great Britain such as the medical devices.

After the end of the transition period (2023-06-30) only those products marked with “UK CA” or “UK NI” instead of “CE” will be accepted on the GB market.

**For continuation of sales into GB all manufacturers of medical devices need to**

**1.)** Register with the MHRA (through online website)

**2.)** Appoint a UK based “Responsible Person”, if a manufacturer is not established in the UK, to register and act on their behalf

**3.)** Comply with the relevant product marking and conformity assessment requirements for medical devices.

The registration process with MHRA needs to be completed during the grace period, individual per class of the device, but latest 2021-12-31.

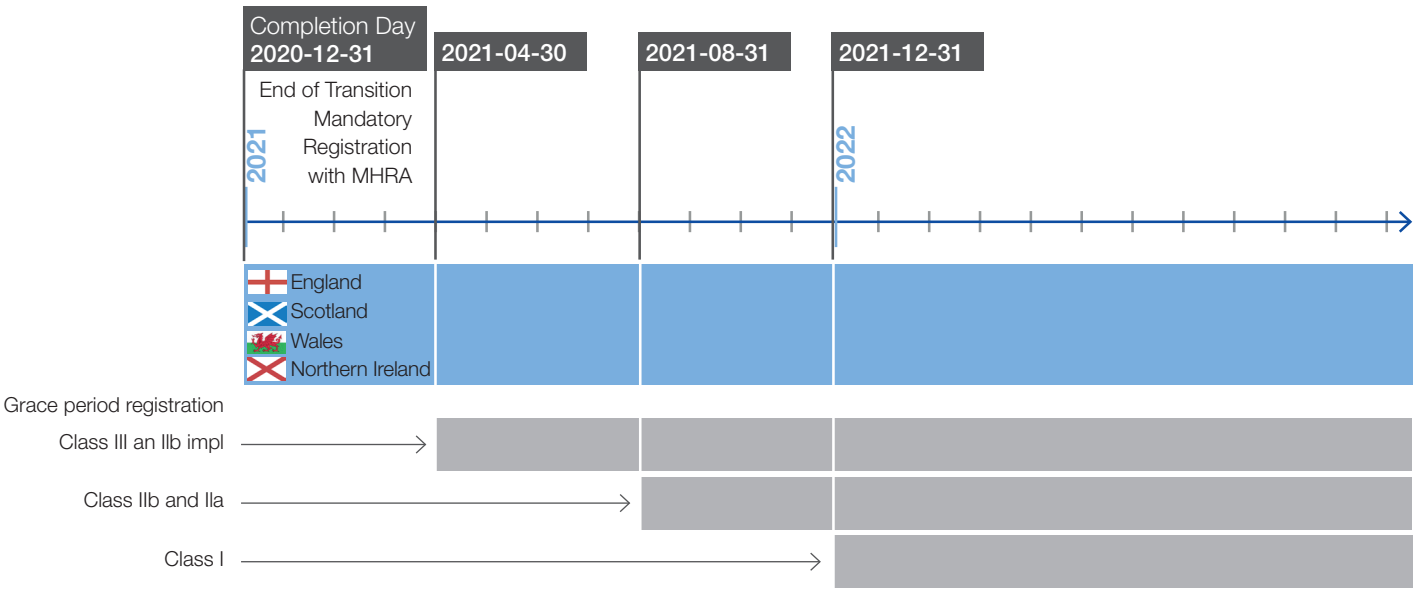
Further information concerning the
- legal situation for medical device in Great Britain →
  and
- the mandatory registration →

is provided by the MHRA.

**Important Information for TÜV NORD CERT Clients:**

All Manufacturers outside EU need a European representative located inside the EU or Northern Ireland. UK-based European representatives are no longer accepted. Please notify TÜV NORD CERT as your Notified Body about changes of your European Representative by using the application form P11F010.

## TIMELINE MANDATORY REGISTRATION WITH MHRA




**For further information please contact our Project Management Medical**
**+49 (0) 201 / 825-2236 or medical@tuev-nord.de.**

24-0527-01/21 Rev.01