Department of Health & Social Care

Edward Argar MP
Minister of State for Health

39 Victoria Street
London
SW1H 0EU

020 7210 4850

The Rt. Hon. Jeremy Hunt MP
Health and Social Care Committee
House of Commons
London
SW1A 0AA

20th October 2020

Dear Jeremy,

I am writing to let that you know that the Medical Devices (Amendment) (EU Exit) Regulations 2020 were laid in Parliament on 15th October 2020.

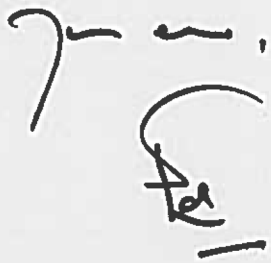
We now have the opportunity to develop a robust, world-leading regulatory system for medical devices that prioritises patient safety. With that in mind, the new regulations are the first step in that process.

In brief, the regulations:

- ensure that the Great Britain (GB) and Northern Ireland (NI) regulatory landscape for medical devices is fit for purpose from 1 January 2021;
- revoke the provisions of the 'no deal' 2019 Regulations that would have given effect in GB to provisions of the 2017 EU Medical Device Regulations and *in vitro* Diagnostic Medical Device Regulations, which will fully apply in NI and EU Member States from May 2021 and May 2022;
- provide a 2.5-year standstill period of unilateral recognition of CE marked devices on the GB market;
- after that standstill period allow 'qualifying Northern Ireland goods' that are medical devices continued unfettered access to the GB market;
- introduce a GB route to market with UKCA (UK Conformity Assessed) marking;
- introduce a new UK(NI) marking that will accompany, but not replace, the CE marking on devices assessed by a UK Notified Body, which will be valid for the NI market but not within the EU;
- specify a requirement for manufacturers who are based outside the UK to engage a UK Responsible Person and register all devices with the MHRA before placing on the GB market;
- specify a requirement for manufacturers who are based outside the UK to engage a UK Responsible Person or an Authorised Representative based in NI and register almost all devices with the MHRA before placing on the NI market; and
- specify a requirement for manufactures who are based in GB to designate an NI or EU-based Authorised Representative in order to place a device on the NI market;
- change the commencement dates for the provisions of the 'no deal' 2019 Regulations which introduced the requirement to designate UK Responsible Persons and register devices with the Medicines and Healthcare products Regulatory Agency (MHRA), so that those commencement dates now run from IP completion day. This will strengthen the

MHRA's oversight and ability to take action when necessary, after the end of the Transition Period.

The Statutory Instrument is being laid under the affirmative procedure. I would welcome the opportunity to discuss these Regulations with you if you have any questions.



EDWARD ARGAR MP