



The European Association Medical
Devices - Notified Bodies

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Team-NB statment on Covid 19

The situation with regards to the Covid-19 outbreak is evolving on a daily basis. During this time the safety and wellbeing of our colleagues, partners and manufacturers is our highest priority.

Notified Bodies are in communication with their designating authorities to share contingency plans to deal with this extraordinary circumstance especially in areas affected by Covid-19.

The outbreak is having an impact on the implementation of both regulation MDR 2017/745 and IVDR 2017/746 due to travel restrictions. The impact is also affecting ongoing surveillance and unannounced audits necessary for conformity assessment to existing Directives.

Please know that our plans try to minimize the risk to all Notified Body and Medical Device Supply Chain personnel while maintaining designation and accreditation requirements.

Please remain in contact with your Notified Body and inform us immediately of any potential issues, such as temporary closure of sites, which may impact our daily plans to fulfil our legal obligations.

In case of any further clarification needed, please contact schlemmer@team-nb.org