Concens Statement on MDR

Regulation (EU) 2017/745

The MDR entered into force on 25 May 2017 and has been in force since 26 May 2020.

Concens products are not classified as medical electrical equipment or systems, nor do they fall within the scope of the EU Medical Device Directive/Regulation or other similar national regulations. The products are components to be built into a piece of medical electrical equipment by a manufacturer. However, we acknowledge the need for medical device manufacturers to be informed about substance content.

The MDR requires the manufacturer of medical devices to state whether the medical device contains Latex or not. Regarding Latex, we can inform, to the best of our knowledge, that none of our Medical approved products contain this substance.

As this is an ongoing process, we will provide information about progress in a timely manner.

Concens A/S, Oddesundvej 1, DK-6715 Esbjerg N (Denmark)

declare that the products

Products: **con35, con50, con60 Inline linear actuators**
(With and without Hall sensor)

following the provisions of Directive(s)

2014/30/EU Electro-magnetic compatibility (EMC)
2015/863/EU Restriction on use of Hazardous Substances in EEE (RoHS)

to which this declaration relates is in conformity and Approvals with the following standards:

- EN 60601-1:A12/2014
- EN 60601-1-2:2015

Esbjerg, Denmark
August 2021

Michael Thode Sørensen
Technical Manager