Coloplast

Ostomy Care
Continence Care
Wound & Skin Care
Interventional Urology

To Whom It Might Concern

June 06, 2019
DKSHo / dksho

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Coloplast MDR Preparations

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Dear

In May 2020, the new and heavily updated Medical Device Regulation (MDR) will reach the "Date of Application" and this will mark the end of the 3-year transition period at which time the Quality Management System, various quality processes as well as all Class I unsterile products needs to be in compliance with the relevant requirements in the regulation.

Products that are backed by a certificate that are still valid under the current legislation will enjoy an additional grace period of (up to) 3 years before they will need to be MDR compliant, furthermore the Unique Device Identification (UDI) part of the MDR legislation has a separate timeline.

Together with our Notified Body – PreSafe DNV – Coloplast has been investing a significant amount of time and resources over the last 4 years in detailed preparation and execution for the continued compliance under the MDR.

This letter serves to state that – with the obvious uncertainty linked to any complex activity – we are confident that we will be able to meet the MDR deadlines and to ensure an uninterrupted flow of quality products to our customers.

Yours sincerely,

Søren Holck

Director Global Quality, Compliance & Systems