



22 October 2020

Clarification on Abena stock (Medical Class 1 devices) after 26th of May 2021

Dear customers and partners,

MDD is moving towards MDR on the 26th of May 2021 after a postponement for one year caused by covid-19.

This has so far involved a lot of work, e.g. updating product labels, technical documentation, certifications etc.

The conclusion from the Danish Medico Industry and the Danish Medicines Agency is clear. Medical Class 1 devices (compliant with MDD) produced **UNTIL** and **INCLUDING** the 25th of May 2021, are allowed to be distributed by ABENA to customers. It also includes containers, but as stated the production date is the essential element.

The main argument here is that the Medical Class 1 devices are within the distribution chain of the manufacturer. Some of you have the role as Distributor in terms of MDR, hence you are allowed to distribute these products. There is no time limit to this transition period.

If you have any questions regarding the above statement please contact your representative at your area.

Yours faithfully
Abena A/S

A handwritten signature in blue ink, appearing to be "Erik Barsøe Bohsen".

Erik Barsøe Bohsen
Managing Director