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CUSTOMER INFORMATION

TRANSITION PHASE - MDR 2017/745 AND IVDR 2017/746

Tuttlingen, 09.04.2020

Dear valued Customer,

Andreas Hettich GmbH & Co. KG as legal manufacturer is required to comply with EU Medical Device Regulation 2017/745 and EU In-Vitro Diagnostic Medical Device Regulation 2017/746 for the following medical devices / in vitro diagnostic medical devices:

Medical Devices	ROTO SILENTA 630 RS, ROTIXA 500 RS, ROTANTA 460; ROTANTA 460R, ROTANTA 460RC; ROTANTA 460RF
IVD Medical Devices	EBA 200; EBA 200S, EBA 270, EBA 280; EBA 280S, MIKRO 220; MIKRO 220R, UNIVERSAL 320; UNIVERSAL 320R, MIKRO 185, MIKRO 200; MIKRO 200R, ROTOFIX 32A, ROTINA 380; ROTINA 380R, ROTINA 420; ROTINA 420R, HAEMATOKRIT 200; HETTCUBE ff.

We started already our transition phase in the beginning of 2019 and are currently under implementation of the new requirements.

Our current EN ISO 13485:2016 Certificate, MDSAP Certificate and CE-Certificate MDD 93/42/EEC Annex II remains valid until the end of the transition phase for our in vitro diagnostic devices under IVDR 2017/746 until 26.05.2022 and for our medical devices under MDR 2017/745 until 26.05.2024.

We will publish the successful transition of our product portfolio on our web page as soon as available.

Mit freundlichen Grüßen / Best regards,
Andreas Hettich GmbH & Co. KG

i.A.

Christian von der Grün
Head of Regulatory & Quality Affairs

Digitally signed by Ichiciuc Gheorghe
Date: 2020.09.15 11:46:59 EEST
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