Dear Customers,

according to contractual agreements as well as applicable regulatory requirements (e.g. Regulations (EU) 2017/745 and (EU) 2017/746), planned significant changes to your approved quality management system or to your products have to be notified to and evaluated by your Notified Body / Certification Body DEKRA Certification GmbH.

For this purpose, we provide you with a form for notification of your changes on our homepage:

https://www.dekra-certification.de/de/benannte-und-akkreditierte-stellen/#element37866101

In the case of product changes, please also provide us with the respective Declaration of Conformity and the current Customer Data Sheet. Use F-091-57 for devices which have already been certified according to (EU) 2017/745 and (EU) 2017/746 and F-091-40 for devices which are still placed on the market according to the transitional rule (EU) 2017/745 Article 120. You have been provided with F-091-40 or F-091-57 as part of the application process.

The form must be completed and sent once with and once without signature to:

med.certification.de@dekra.com

The implementation of the planned substantial changes may only take place after approval by the body. Therefore, please allow sufficient lead time for the evaluation by DEKRA Certification GmbH when submitting.