Information on price adjustments in the Area of Medical Devices

Dear Ladies and Gentlemen,

As a Notified Body for medical devices and Certification Body for QM Systems, we can look back on a very long and successful Business relationship with you.

TÜV NORD stands for quality and a business partner you can rely on.

As we want to continue to support you with our service portfolio in the field of Medical Devices in the future, we are gradually adjusting our prices from this year onwards. Please refer to the attached table for a detailed overview.

Service*	Daily rate in Euro	Daily rate in Euro
	from 2019	from 2020
Audit EN ISO 13485 (including KRINKO requirements)	1600	1700
Audit EN ISO 9001 (in the field of medical devices)	1600	1700
Audit RL 93/42/ECC (also unannounced)	1700	1900
Audit RL 90/385/ECC (also unannounced)	1700	1900
Evaluation of Technical Documentation	1850	1900
Evaluation of design dossiers	1850	1900
Evaluation of validations	1850	1900
Evaluation of special events (e.g. incidents, inquiries from authorities, processing of changes)	1850	1900

*includes all necessary steps such as preparation and follow-up, release, certification, evaluation of the clinical evaluations etc.. Invoicing is based on actual expenditure. The individual aspects are specified more precisely in your offers/appointments.

Stricter requirements in the accreditation and designation procedure lead to increased requirements in order to be able to maintain the status of designation and accreditation. Increased demands on the conformity assessment procedures and certifications of quality management systems, extensions of the participation of notified bodies in conformity assessment procedures and tightening of the competence requirements on the part of the employees of certification bodies also lead to an additional burden on our Notified Body.

We continue providing you with our high level of quality and to further improve our service. It is our aim to further develop our services with regard to the certification of quality management systems, also in the area of reprocessing in hospitals, as well as the

participation in conformity assessment procedures in the area of EU 2017/745 (MDR) & EU 2017/746 (IVDR).

We regret the short-term information about this important adjustment and ask for your understanding.

We hope to continue to count you among our satisfied customers in the future and look forward to further cooperation.

Yours sincerely

Your Medical Team
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