

FEES FOR CONFORMITY ASSESSMENT ACTIVITIES MEDICAL DEVICES CERTIFICATION – REGULATION 2017/745 (MDR)

APPLICATION FEE

Description	Flat fee depending on risk class device	
Administrative fee to start the Certification process	Class I	3.400,00 € *
	Class IIA	3.700,00 € *
	Class IIB	4.000,00 € *
	Class III	4.300,00 € *
Administrative fee to start the Extension/major change process	Class I	1.200,00 € *
	Class IIA	
	Class IIB	
	Class III	

*CQY takes into account the interests of small and medium-sized enterprises (as defined in Recommendation 2003/361/EC), applying a 30% discount on the "Application fee".

PRODUCT TECHNICAL DOCUMENTATION ASSESSMENT

Description	Fee per hour
Product Expert Assessment	350,00 € **
Clinical Expert Assessment	350,00 € **
Clinical Specialist Assessment	375,00 € **
PSUR (Periodic Safety Update Report) Periodic Assessment	350,00 € **

**plus 50% for internal activities and back-office support

QMS (QUALITY MANAGEMENT SYSTEM) AUDIT

Description	Fee per hour
On site/off site announced audit	334,00 € ***
Unannounced audit (minimum 16 hours)	334,00 € ***

*** plus 50% for internal activities and back-office support

- Travel time and expenses not included
- Fee is intended per Auditor