Saatja: Chevalier, Aleksandra <Aleksandra.Chevalier@fortrea.com>
Saadetud: 03.04.2024 17:55
Adressaat: TA Info <info@terviseamet.ee>
Teema: ASR report for pre-market medical device study in Estonia query
Tähtsus: Kõrgeim

Dear Sir/Madam,

Hope this email finds you well.

We would like to confirm two topics related to pre-market device studies in Estonia.

1. Could you please provide reference from MDR on the content of ASR report for pre-market device study in Estonia?

2. Our Sponsor have decided to have 1 ASR per product per protocol per country. Could you please verify/confirm there is no regulation in Estonia or Europe (MDR 745-20017 requirement) against this decision?

Thank you

Best Regards,

Aleksandra Chevalier, MPharm
Drug Safety Associate, Drug Safety

E: fortrea.comFortrea Development Ltd