IMDRF International Medical Device Regulators Forum

New aspects in MD regulations in the Russian Federation

Amiran Preobrazhenskiy

PreobrazhenskiAV@roszdravnadzor.ru

Amendments in the scheme of MD pre-market approval

Order of the Ministry of Health from 03.06.2015 № 303н

« On amendments into the Order of the Ministry of Health from 21 december 2012 г. N 1353н « On improvement of the order of organization and conducting the expertise of quality, effectiveness and safety of MD»

Entered into force since 17.07.2015

The process of pre-market approval of MD of 1st class of risk will be proceeded in 1 stage

THANK YOU