

COMMENTS FROM THE EUROPEAN UNION REGARDING NOTIFICATION

G/TBT/N/RUS/51

Draft decision of The Board of the Eurasian Economic Union "On the establishment of the rules of conducting technical tests of medical devices"

G/TBT/N/RUS/52

Draft decision of The Board of the Eurasian Economic Union "On the rules of registration and of the safety, quality, and efficiency inspection of medical devices"

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Draft decision of The Board of the Eurasian Economic Union "On the special production mark of medical devices on the market of the Eurasian Economic Union"

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Furthermore, the EU would like to point out that the use and recognition of international standards (especially ISO standards) and best practices (notably for the recognition of clinical information), specified in a number of technical guidance documents of GHTF/IMDRF¹, are essential for market access for medical technologies around the world. In this respect, the EU would also like to refer to Article 2.4 of the TBT Agreement which states that "*[w]here technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems*".

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