

Mrs. Elizabeth McGrath

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Assunto: Personalized Medical Devices

Dear Mrs. Elizabeth McGrath

In the context of the public consultation of the document proposed by the International Medical Device Regulators Forum, the *Ordem dos Enfermeiros* (Portuguese Order of Nurses) welcomes the initiative aimed at the international harmonisation of definitions relating to Personalized Medical Devices.

In view of the exponential technological progress, it is never too important to stress that it is essential for all competent authorities to monitor and further develop an international convergence of the different jurisdictions, thus obtaining in that way a gain for the regulatory authorities, industry, and in particular for patients to have a broader access to new technologies in a timely, safer and quality manner.


Thus, in analysing the above-mentioned document, one welcomes the goodness of the concepts expressed in it, however, and in the same way as this Regulatory Order has already done with the competent Portuguese entities, it is proposed to change the designation of **medical devices** for **clinical devices**, taking into account that the use of such devices is not restricted to physicians but also to other health professionals, namely Nurses.

This designation, in our view, has a broader scope of application.

The *Ordem dos Enfermeiros* also stresses the fact that medical devices must be produced in such a way that their use is the safest, taking into account the conditions and intended purposes, so as not to compromise either the clinical status or the safety of the patients, thus minimizing the potential risks of its use.

Kind regards,

President of Ordem dos Enfermeiros



Ana Rita Pedrosa Cavaco



Name/Organization	Section	Comments	Proposed Change	WG Resolution
Ordem dos Enfermeiros (Portuguese Order of Nurses)	Administrative Center	The Ordem dos Enfermeiros welcomes the initiative of the International Medical Device Regulators Forum to harmonize the definitions of Personalized Medical Devices.	The Ordem dos Enfermeiros proposes to change the designation of medical devices for clinical devices , taking into account that the use of such devices is not restricted to physicians but also to other health professionals, namely Nurses. This designation, in our view, has a broader scope of application.	