The European Association of Medical devices Notified Bodies

Team-NB Position Paper

Editor :	**Team-NB**	Adoption date to be confirmed after vote	Version 1

Notified Body position paper on transitional period for implementation of MDCG guidances and best practice documents

Disclaimer:

1. MDCG Guidance are not introducing new legislative requirements
2. MDCG Guidance are intended to give further guidance to the stakeholders such as manufacturers notified bodies etc.
3. MDCG Guidance are not legally binding

The purpose of this document is to establish a harmonized approached in the implementation and application of the MDCG guidance documents by Notified Bodies within their quality management systems/operating processes.

1. Executive Summary

In the context of the European Medical Devices Regulation MDR (EU) 2017/745 and IVDR (EU) 2017/746, when involved in the conformity assessment procedure, Notified Bodies shall verify the continuous compliance with legal obligations for medical devices.

The goal of this position paper is to provide Team NB harmonised approach for complying with the following requirements:

- MDR /IVDR Annex VII, 4.5.1 requirement: The notified body shall, where relevant, take into consideration available CS, guidance and best practice documents and harmonised standards, even if the manufacturer does not claim to be in compliance.
- MDR/IVDR Annex VII, 1.6.2 requirement: The notified body shall take into consideration guidance and best practice documents.

2. Proposal for Notified Bodies harmonized approach on the uniform application of transitional period

Notified Bodies propose a uniform transitional period for implementing MDCG guidances into the Notified Body's Quality Management System as below:

1. Up to 4 months from MDCG guidance publication date to complete a thorough gap analysis
2. Up to 8 months from MDCG guidance publication date for a full impact assessment and updates to QMS documents, IT systems, processes etc
3. Up to 12 months from MDCG guidance publication date for roll-out of the changes including staff training

3. In conclusion

A consistent approach in transition periods for the implementation of MDCG guidances and other documents (as appropriate) will help standardise the implementation of such documents by Notified Bodies and provide predictability to other stakeholders such as the Regulatory Authorities and Manufacturers.