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Regulatory Intelligence Paper

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Note: This paper is a support document which helps companies to be compliant according to ISO 13485: 2016 (Chapter 5.6 Management Review). But Regulatory Globe GmbH does not give any guarantee regarding completeness and correctness of this document and is also not responsible for any missing information who can affect the user/company. Each user/company is responsible by them self to have all required regulations and standards in place.

1. Europe

Topic 1:	**Position Paper on New MDR Transition Timelines and Notified Body Capacity**		
Source:	TEAM-NB		
Relevant for:	☒ Economic Operators		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **View on New MDR Transition Timelines and Notified Body Capacity**		
Scope / Description:	*Team-NB specify in this paper their views on the amended timelines with regards to benefits for the European patients and as the continuity in the availability of essential medical devices in the European market.*		
Information Issued:	August 10, 2023		
Implementation deadline:	For information only		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 2:	**Transfer Agreement for Surveillance of Legacy Devices**		
Source:	TEAM-NB		
Relevant for:	☒ Economic Operators		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Template Agreement**		
Scope / Description:	*Team-NB adopted a template agreement specifying the terms of the transfer of the surveillance according to Regulation 2017/745 for legacy devices.*		
Information Issued:	August 14, 2023		
Implementation deadline:	For information only		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			

Topic 3:	**Flowchart to assist in deciding whether or not a device is covered by the extended MDR transitional period**		
Source:	EU doc.room		
Relevant for:	☒ Manufacturers		
Could affect following device type areas:	☒ General		
Key Topics:	▪ **Flowchart for decision-making**		
Scope / Description:	*Conditions and deadlines for placing legacy devices and class III custom-made implantable devices on the market or putting them into service in accordance with Article 120 MDR, as amended by Regulation 2023/607.*		
Information Issued:	August 23, 2023		
Implementation deadline:	N/A		
Company Assessment: (Must be judged by the Company itself)			
Action required?	Yes: ☐ No: ☐	**Company Impact:**	Low: ☐ Middle: ☐ High: ☐
Potentially affected department:	Engineering: Yes: ☐ No: ☐	Quality Management: Yes: ☐ No: ☐	Production: Yes: ☐ No: ☐
	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐	tbd: Yes: ☐ No: ☐
Management conclusion / decision:			