MD REGULATORY DIGEST

FOCUS ON

MDR TIMELINE

		26/05/17	**The MDR enters into** force 20 days after its publication and is partially applicable.		
		26/11/17	Art. 35 to 50 shall apply: First **NB submissions** under MDR.	Art. 123.3.a)	
		19/01/19	Notification of **BSI UK (NB 0086)** under MDR.[1]		
Art. 123.3.i)	Art. 120.12 shall apply: Until the Commission has designated issuing entities, GS1, HIBCC and ICCBBA shall be considered to be designated UDI issuing entities.	26/05/19			
		25/05/20	**Eudamed** is functional.[2]	Art. 34	
		26/05/20	**DATE OF APPLICATION**: MDR fully applies, End of the transitional period.	Art. 123.2	
			End of issuance of new MDD certificates.	Art. 120.1	
			A device with a valid MDD certificate issued prior to 25/05/2017 may only be **placed on the market or put into service** provided that from 26/05/2020 it continues to comply with MDD, and provided there are no significant changes in the design and intended purpose. However, the **requirements of MDR relating to PMS, market surveillance, vigilance, registration of economic operators and of devices** shall apply in place of the corresponding MDD requirements.	Art. 120.3	
Art. 123.3.f	Art. 27.4 shall apply for **class III devices & implantable devices**: **UDI carriers** shall be placed on the label of the device and on all higher levels of packaging.	26/05/21			
		26/11/21 (Eudamed + 18months [2])	Art. 29.4 shall apply: Before placing a device on the market, manufacturers shall ensure that the information on **Eudamed** on their devices referred to in **Annex VI.A.2** is complete, correct and updated by the relevant party, except section 2.2 (NB certificates information).	Art. 123.3.e)	
			Art. 56.5 shall apply: **Notified bodies** shall enter in Eudamed any information regarding **certificates** issued.	Art. 123.3.e)	
		27/05/22	**MDD certificates** issued in accordance of **Annex IV** become **void**.	Art. 120.2	
Art. 123.3.f	Art. 27.4 shall apply for **class IIa & IIb devices**.	26/05/23			
Art. 123.3.g	Art. 27.4 shall apply for **reusable class III and implantable devices** that shall bear the UDI carrier on the device itself.				
		27/05/24	MDD certificates issued from 27/05/2017 become void. **All devices newly placed on the market must be in conformity with the MDR.**	Art. 120.2	
			MDD devices **already placed on the market** may continue to be made available or put into service until 27/05/2025.	Art. 120.4	
Art. 123.3.f	Art. 27.4 shall apply for **class I devices**.	26/05/25			
Art. 123.3.g	Art. 27.4 shall apply for **reusable class IIa & IIb devices** that shall bear the UDI carrier on the device itself.				
		27/05/25	MDD devices that weren't made available or put into service shall be **withdrawn from the market**.	Art. 120.4	
Art. 123.3.g	Art. 27.4 shall apply for **reusable class I devices** that shall bear the UDI carrier on the device itself.	26/05/27			

[1] This information shall be moderated by Brexit (see my previous Digest).
http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notification.pdf&dir_id=34&ntf_id=288798

[2] If Eudamed is not functional on 25/05/2020, Articles 29.4 & 56.5 shall apply **18 months after** the day it becomes functional.

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[NOT MDR]
Packaging for terminally sterilized medical devices: ISO 11607-1:2019 & ISO 11607-2:2019 published
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https://www.iso.org/standard/70800.html

European Commission

European Commission: **MDCG Guidance on Content of the certificates, voluntary certificate transfers published**
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