May 21, 2019

EUROPEAN MEDICAL DEVICE REGULATION

CASE - BEST PRACTICES OF MDR IMPLEMENTATION

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Medtronic
Further, Together

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CASE STUDY

COMPANY: ABC

2 Business Units, 2 QM Systems , 2 Notified Bodies

- 5 Class III devices
- 5 Class III Tech. Doc. files
- 2 Class III products : 80 class III revenue
- 1 HIPO innovative Class III product in development

- 50 Class II b/a
- 1 Class II b implant, 1 Tech. Doc. file
- 8 Class IIa/b Tech. Doc. Files
- 20 class II a/b products: 80 revenue
- 10 HIPO iterative class II non implantable in development

- 15 class I
- 10 Class I Tech. Doc Files
- 5 class I reusable surgical instruments

Medtronic
Further, Together

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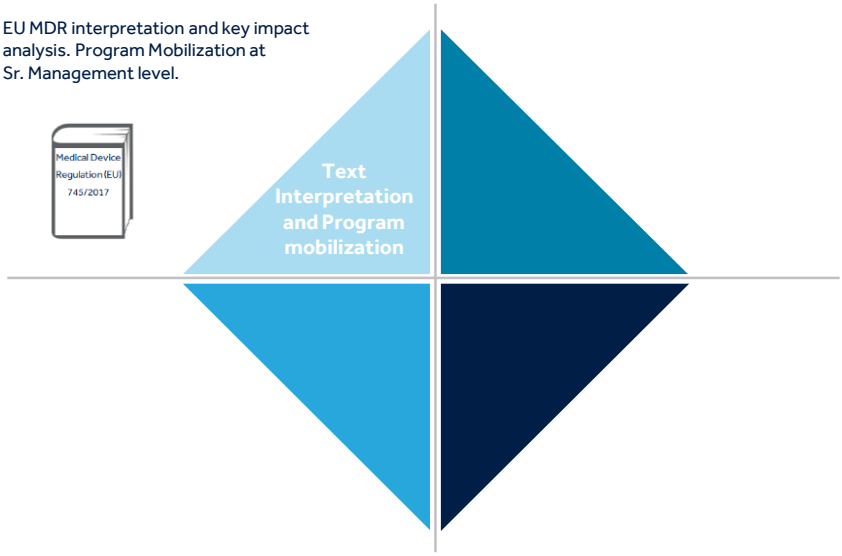
FOUR IMMEDIATE FOCUS AREAS
REGULATORY AFFAIRS: THE SPEARHEAD

EU MDR interpretation and key impact analysis. Program Mobilization at Sr. Management level.



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EU MDR IMPLICATIONS
NEW AND LEGACY PRODUCTS ARE AFFECTED

Key EU MDR Changes	Business Implications	Implicated Business Functions
Restricted Equivalence Claim (in particular Class III and Implants) **New (up-) classification** **Hazardous Substances** Tightened Requirements	Revenue impact from loss in portfolio	R&D Supply Chain
„Scrutiny" – EU Panel Clinical data review **Notified Body Design Review for** Class IIb Implants	Increased Time To Market	R&D Regulatory Clinical
Technical Documentation, DoC New Format and Content, UDI linkage **Expanded Labelling Requirements** (including Implant-Information)	Administrative Burden	R&D Regulatory, Tech. Communication, Production/Supply Chain
QM-System: PMS, Vigilance, PSURs, Trend Reports **Clinical Study Reports Summary of Safety and Performance** **EUDAMED:** Economic Operator registration, UDI linked device registration	Increased Transparency and Documentation	Quality Medical safety Regulatory Regulatory, Supply chain

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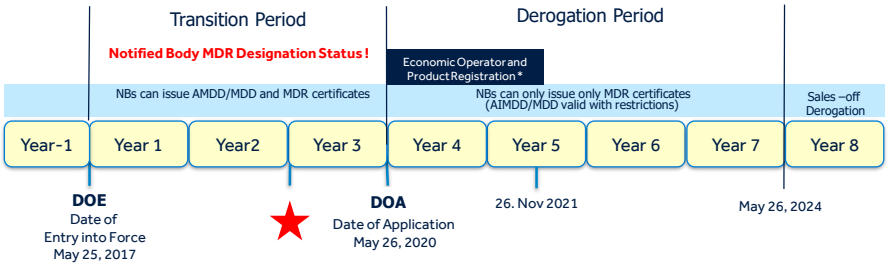
GLOBAL PORTFOLIO IMPACT

EU MDR PROPOSED CHANGES ARE EXTENSIVE

EU MDR affects global CE-mark based regulatory registrations

EU MDR TRANSITION PROVISIONS



*if EUDAMED is functional at DOA

UDI Labeling:

a. Class III +Implants: 1 year after DOA
b. Class IIb/ IIa : 3 years after DoA
c. Class I: 5 years after DoA

Direct UDI Labeling of reusable devices 2 years after the relevant date for the respective product class.

NOTIFIED BODIES – STATE OF THE PLAY

Received Applications at DG Sante	Joint on-site Audits	Received CAPA Plans at JAT	Final JAT Assessments	Notification in NANDO
47 (MDR: 38)	32 (MDR: 26)	11 (MDR: 9)	2 (MDR: 2)	1 (MDR: 1)

Expectation: 10 – 12 Bodies notified in NANDO by the end of 2019

CONFORMITY ASSESSMENT – RECENT NEWS

MDCG 2019-3

The CECP (Clinical Evaluation Consultation Procedure) acc. to Art. 54 is not applicable to already AIMDD/MDD certified devices.

Concerned devices are:

(a) class III implantable devices, and

(b) class IIb active devices intended to administer and/or remove a medicinal product, as referred to in Section 6.4 of Annex VIII (Rule 12).

https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

LABELING/SYMBOLS – RECENT NEWS

Final Selected MDR Symbols

Selected Description	Medical device	Contains human blood or plasma derivatives	Contains a medicinal substance	Contains biological material of animal origin	Contains biological material of human origin	Importer	Distributor	Contains hazardous substances	Contains nano materials	Sterilized using vaporized hydrogen peroxide
Selected Symbol	MD			BIO	BIO					STERILE VH2O2

Final Selected MDR PIC Symbols

Selected Description	Medical device	Person identification	Patient information website	Date	Health care center or doctor	Unique Device Identifier
Selected Symbol	MD			31		UDI

Medtronic developed and validated symbols

Additional MDR symbols:

The following Sterile Barrier Symbols (SBA) and additional MDR symbols have been selected.

Sterile Barrier Symbols

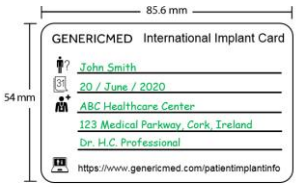
Selected Description	Single sterile barrier system	Double sterile barrier system	Single sterile barrier system with protective packaging inside	Single sterile barrier system with protective packaging outside
Selected Symbol				

Additional MDR Symbols

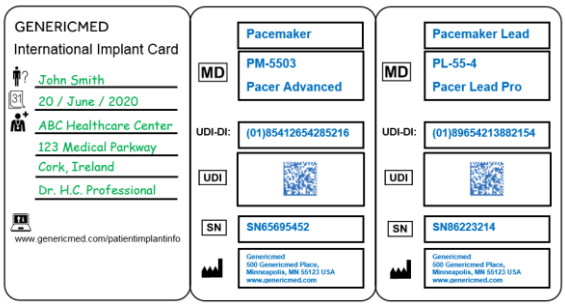
Selected Description	Single patient - multipe use	Translation	Repackaging
Selected Symbol	1	A文	

Use of above symbols is less common.

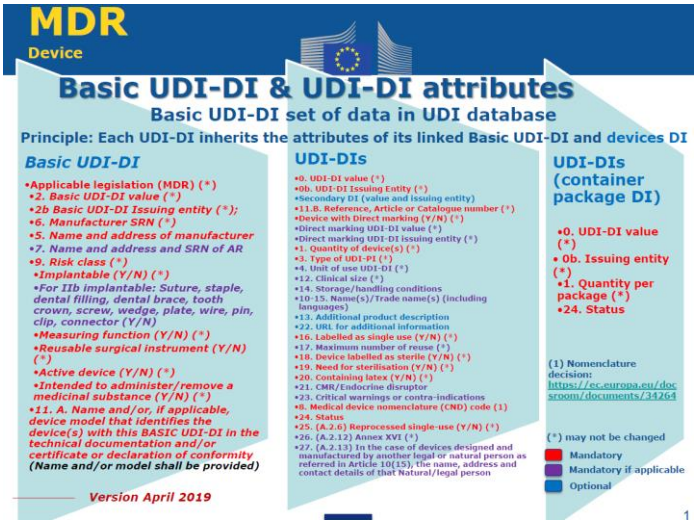
IMPLANT CARDS – RECENT NEWS



Back – Not to Scale (Blank – Serial printed content in product



UDI – RECENT NEWS



UDI – RECENT NEWS

Commission on Nomenclature

In accordance with Articles 23 IVDR and 26 MDR, having due regard to the views provided by the MDCG, **the CND nomenclature, to be mapped to the GMDN nomenclature, will be made available in the future Eudamed.**

https://ec.europa.eu/docsroom/documents/34264?locale=en

MDCG - Registration of device data elements and legacy devices

MDCG-2019-4: Device registration applies 18 months after the general application date or, if EUDAMED is not fully functional on time, from 24 months after the date of publication of the notice on Eudamed functionality.

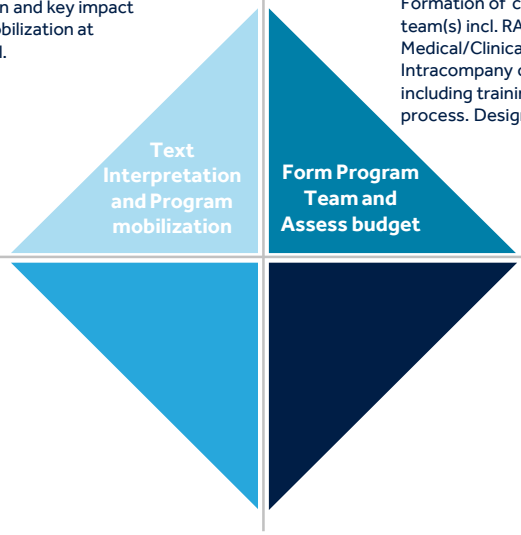
MDCG 2019-5: MDCG considers it appropriate to adapt the Eudamed design to allow the registration of legacy devices in Eudamed in the absence of a (Basic) UDI-DI.

https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

FOUR IMMEDIATE FOCUS AREAS

COLLABORATE APPROACH OF MANY FUNCTIONS

EUMDR interpretation and key impact analysis. Program Mobilization at Sr. Management level.



Formation of cross functional program team(s) incl. RA, QA, R&D, Medical/Clinical, Marketing, Finance. Intracompany communication plan including training and risk escalation process. Designation of responsibilities.

ABC CROSS BU COLLABORATION

Management Steering Committee

Program Team
Program Management, Text Interpretation, Communication

	BU 1	BU 2
Regulatory:	NB Readiness, (Re)-Certification Plan, Technical Documentation/ DoC update	
Quality:	NB Audit Planning, Procedure Update: PMS (PSUR), Vigilance (MIR)	
Clinical:	Sufficient Clinical Data, Equivalence, SSCP, CIT processes	
Labelling:	Label and IFU Requirements, Symbols, eManual website, Implant Cards	
Hazardous Substances:	Identification, Risk Assessment/Justification, Labelling	
EUDAMED/UDI:	(Basic) UDI –assignment/labeling, Econ. Operator/Device Registration, PMS & Clinical	

ABC decided to have a cross BU approach on pre-defined implementation activities.

FOUR IMMEDIATE FOCUS AREAS
MITIGATE FINANCIAL IMPACT

EUMDR interpretation and key impact analysis. Program Mobilization at Sr. Management level.

Text Interpretation and Program mobilization

Form Program Team and Assess budget

Portfolio Rationalization

Formation of cross functional program team(s) incl. RA, QA, R&D, Medical/Clinical, Marketing, Finance. Intracompany communication plan including training and risk escalation process. Designation of responsibilities.

RA/Finance product portfolio analysis primary budget estimation. Program monitoring scorecards.

ABC KEY LEVERS TO MITIGATE FINANCIAL IMPACT

1. TECH DOC PRIORITIZATION
- Prioritization at Tech File level
- Business Case for Each Tech File

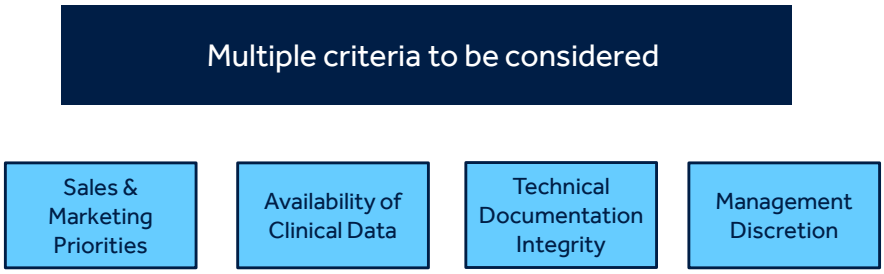
2. PORTFOLIO RATIONALIZATION
- Must Have: REMEDIATE or REPLACE
- Can go : RETIRE
- TBD Products: REMEDIATION ?

3. STRETCH COMPLIANCE TIMELINE
- Spread spending over multiple years
- Renew under old MDD till FY 19/20
- Maximize use of MDD certs (2021-24)

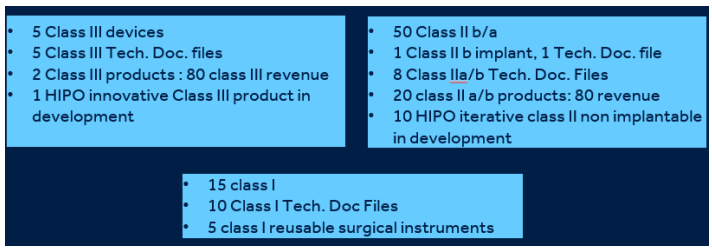
4. GO AFTER BIG TICKET COST DRIVERS
- Clinical Investigations
- Hazardous Substances
- Labelling

ABC decided to focus on four areas to mitigate cost impact

PORTFOLIO RATIONALIZATION AND PRIORITIZATION



ABC PRODUCT PORTFOLIO ANALYSIS

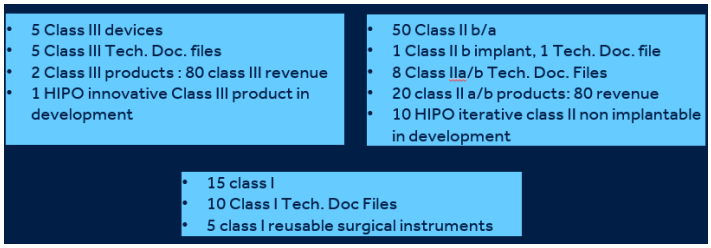


ABC found after discussions with their NBs that only one of their high seller class III products meets the new expectations for clinical data, i.e. is supported by clinical investigation data.

They therefore decided to **re-certify** the other class III high seller product **under MDD** and initiate a post–market clinical investigation to support its MDR certification later during the derogation period with this study.

However, they will **discontinue to market the other 3 low seller class III** devices and **focus on the class III HIPO product in R&D**.

ABC PRODUCT PORTFOLIO ANALYSIS



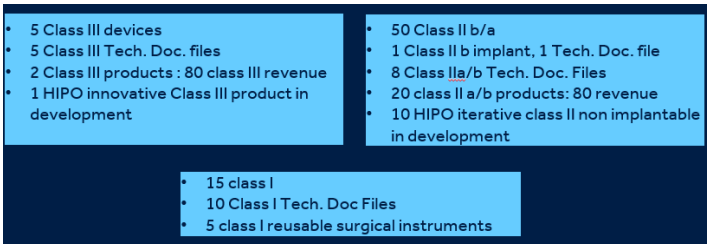
ABC will also **collect more clinical data for their implantable class IIb implant** product as its sales contributes significantly to company revenue.

Since this product is already on the market for a long time ABC considers to **conduct a survey study** at three clinics where the product has been frequently used as already pre-discussed with the respective NB.

Further ABC plans to support the MDR certification of the **other class II b/a products** with existing clinical evaluation data.

Final decisions were taken based on discussions with the company's NB identifying **common understanding what "sufficient clinical data"** are expected for these products.

ABC PRODUCT PORTFOLIO ANALYSIS



ABC also intends to keep their class I products on the market.

Accordingly they will update the TD and labeling of these products to the MDR requirements before DOA.

For their reusable surgical instruments they will apply for MDR certificate within the 3 year transition period. However the MDR readiness may well jeopardize this plan.

FOUR IMMEDIATE FOCUS AREAS

Cross BU Notified Body Approach

EUMDR interpretation and key impact analysis. Program Mobilization at Sr. Management level.

Text Interpretation and Program mobilization

Formation of cross functional program team(s) incl. RA, QA, R&D, Medical/Clinical, Marketing, Finance. Intracompany communication plan including training and risk escalation process. Designation of responsibilities.

Program team and Communication Plan

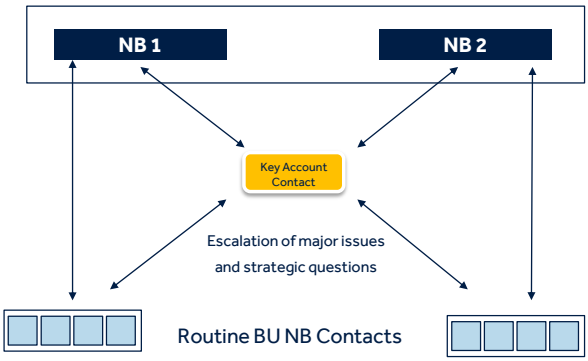
Recertification Plan and Notified Body approach

Coordinated approach of BUs. Early contact to NBs regarding their MDR designation, legacy device clinical data requirements and (re)-certification planning for QMS and product certificates.

Portfolio Rationalization and Budget Plan

RA/Finance product portfolio analysis primary budget estimation. Program monitoring scorecards.

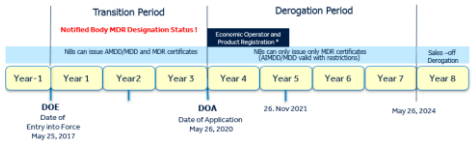
ABC NOTIFIED BODY COMMUNICATION MODEL



ABC decided to have **one contact person for both NBs** the company has contracted to discuss strategic question and major issues with high level NB management.

At the same time ABC continues to execute operational and tactical detailed activities directly between BU experts and respective NB counterparts.

ABC (RE)-CERTIFICATION PLAN



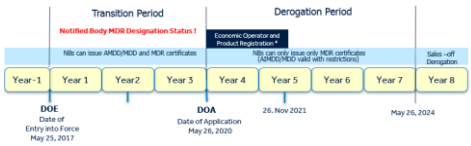
ABC considers the following (re) certification process:

1. They will apply for **MDR certification** of their **high seller class III product** supported by clinical investigation data **before DOA** and use this product technical documentation as a template for their QMS MDR certification.

2. They will also apply for **QMS MDR certification before DOA** to support the MDR certification of their HIPO class III device scheduled shortly after DOA. However **their MDD QMS certificates will be renewed** as well to make full use of the Derogation Period.

3. The **other high sales class III product and the implantable class IIb product** will be MDD re-certified before DOA and transferred to MDR during the Derogation period adjusted to the timeline when the post – market clinical study or the survey studies are finished.

ABC RE-CERTIFICATION PLAN



4. **Class IIa/b products** will be **moved step by step from MDD to MDR** as soon as their labeling and technical documentation including CER has been updated to be MDR compliant after the MDR QMS certs have been granted.

   Some products with low sales volume may be discontinued in case NBs require additional studies for clinical data. **The post DOA MDD QMS certificate expiry date shall be met.**

5. **All class I** technical documentations and labeling will be made MDR compliant **updated before DOA**. MDR DoCs will be issued accordingly.

   In case of reusable surgical instruments DOA cannot be issued until these devices are certified by the NB.

Thank you for your attention !