Notification Regarding

the changes that may take effect as a result of applying of MDR (REGULATION (EU) 2017/745)

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The changes that may take effect as a result of the applying of the MDR (REGULATION (EU) 2017/745) are divided into three types:

1. Changes that require applying to the Administration of Medical Devices Variation.
2. Changes that do not require applying to Administration of Medical Devices Variation.
3. Changes related to the classification of the Medical Devices.

First: Changes that require applying to the Administration of Medical Devices Variation:

	The change of	Changes details	Procedure action
1.	Instruction for use (IFU)	Additional information and clarification For example, intended user, contraindication where applicable, information about CMR/ED substances, information to be supplied to the patient with an implanted device, explanation of new symbols that appear on the label, etc.	The change shall be studied by Administration of Medical Devices Variation to verify whether or not this change is significant In case of it is considered insignificant change: An approval shall be issued to the variant In case of it is considered a significant change: The company shall be committed to submit a new registration file
2.	Intended Purpose	Minor update of intended use with no change to approved scope. For example, rephrases intended use For clarity, based on existing clinical studies, this will appear on the (IFU)	The change shall be studied by the Administration of Medical Devices Variation and the change shall be evaluated by the specialized scientific committees and/or a statement shall be submitted by the certificate issuing authority to verify that the intended use has not been changed or that it is only a matter of re-phrasing. In case of change only relating to rephrasing of the content, it shall be considered a **(Minor Artwork update**). In case of change is significant, it will be considered a **(Major Artwork update)** **Note:** Companies shall be permitted to submit combined requests for a set of devices in case of change is general and not relating to a specific device
3.	Design and Intended purpose	Significant change in design or a significant change in the intended purpose	The change shall be studied by the Administration of Medical Devices Variation and be evaluated by the specialized scientific committees and/or a statement shall be submitted by the certificate issuing authority to verify whether or not this change is significant In case of it is considered insignificant change: An approval shall be issued to the variant

			In case of it is considered a significant change: The company shall be committed to submit a new registration file

Second: Changes that do not require applying to the Administration of Medical Devices Variation:

The following changes are not to be reported to the administration of medical devices variation and it is prohibited for the concerned departments and authorities to instruct the company to do so.

	The change of	Change details
1.	Labels	1. Additional information, including UDI, new symbols. For example, indication that a product is a Medical Device (MD) or that it contains CMR/ED substances, etc. 2. If there is no expiry date, the date of manufacture has to be reflected as: YYYY-MM-DD 3. Update Home-Use Device Labeling to be worded for Laypeople
2.	Notified body certificate	Additional information For example, UDI, the registration number of the manufacturer (if already issued) ,etc.
3.	Declaration of conformity	Additional information Including UDI, registration number of manufacturer and of European authorized representative (if already issued), etc.
4.	Certificate of Free Sale (CFS)	New data Including Basic UDI, notified body certificate number. Possible new layout for the CFS as MDR foresees the possibility to adopt a model format
5.	MDD/AIMD certificates	No issuing of new certificates, including modified, amended or supplemented certificates is allowed under MDR The Notification of changes between the manufacturer and the notified body according to the AIMD/MDD Will be verified by the notified body. The outcome of this verification will determine whether a certificate in accordance to AIMD/MDD remains valid
6.	Instruction for use (IFU)	1. Addition of appropriate Device and Software/ Accessory Selection to IFU 2. Addition of additional Device Information to IFU 3. Addition of Information on Hazardous Radiation to IFU 4. Addition of Instructions to IFU if product is Damaged /Opened 5. Addition of device Disposal to IFU 6. Addition of Device Malfunction Reporting Statement to IFU 7. Addition of reuse reconditioning requirements to IFU

Third: Changes related to the classification

(Up classification/or down classification)

	Status	Procedure
1.	For already registered Medical Devices	The certificate issuing authority shall be addressed to verify the reason for modifying the classification to determine whether the modification is considered a variant or not If it is considered as a variant: The file shall be submitted to Administration of Medical Devices Variation: and the general administration of pharmaceutical vigilance shall be applied. If it is not considered as a variant: A new registration file shall be submitted and it shall granted a one-year grace period for import or production as of the date of submitting the registration file.
2.	For items up classified from non-regulated (according to MDD 93/42/EEC) to regulated class (according to EU MDR 2017/745)	A new registration file shall be submitted and it shall be granted a one-year grace period for import or production as of the date of submitting the registration file.