Johnson & Johnson comments on the consultation on the Guide to Distribution of Medical Devices.

Section	EB Comment
General	This document is currently in draft, and references the MDR/IVDR as draft documents, will this reference to the status of the regulations change prior to publication?
General	The document does not make any reference to the timing for implementation, is there an inference that the implementation of this draft is aligned with the implementation timing for MDR/IVDR?
General	Will certification/authorisation be issued to show compliance?
Page 4: Definitions	Clarification on products that are not physically stored/handled in Ireland (i.e. product coming direct from our central warehouse in Belgium directly to the customer). A financial flash transaction is done to J&J Ireland at the point of sale, does this make J&J Ireland a distributor?
Page 4: Definitions	Suppliers from Switzerland require clarification as the J&J Ireland distribution center receives product primarily from Switzerland. Is the definition across the EU or the EEA?
Page 4: Definitions	Importer definition mentions “Union Market” while on p14 it is EEA.
Page 5: Article 14, Paragraph 2 Also page 15: Receiving	Is the fact we have an Intercompany Quality Agreement between J&J Ireland and our J&J business’s sufficient to detail why each product is not checked for a CE mark/IFU etc.?
Page 7: Implementation of QMS	All critical steps of the distribution process and significant changes are outlined in different internal documents (e.g. ICQA, Quality Manual etc.). Will this be sufficient? And where relevant validated? What is relevant and what is considered validated – could this be by the change control process?
Page 8: Traceability	Consideration needs to be made for products without LOT numbers etched on them, in this instance we remove all products if affected by a FSCA. Also for products within instrument sets, they are not traced on a LOT level within Loan or Consignment sets., so would all sets would be removed.
Page 8: Traceability	Goods Receipt check is not currently recorded on a separate form, the signature and confirmation of check is written on the Delivery Note. Other examples should be considered as goods receipt is frequently recorded electronically. Suggest other alternative items that could be recorded on forms, such as pest control inspection checks.
Page 8	Refer to ISO 13485 which provides information on quality systems for suppliers of medical devices and is more specific than the general requirements of quality systems specified in ISO 9001 – given that

	this document is a guidance, can it be inferred that both ISO documents are only being given as a point of reference and that it is not planned to enforce certification to ISO on Distributors?
Page 8	Superseded master copies of procedures should be maintained for a period of at least 6 years – the 6 year requirement is not specified in EU MDR / IVDR, or in ISO. Suggest that this is modified to 'retained in line with company policies, with consideration for the shelf-life of the product including device usage.
Page 8: Periodic Review	This review should be documented and any recommendations should be implemented – ADD 'in line with documented change control requirements'.
Page 8: Reference to SOPs	It is particularly important that SOPs relating to activities in certain areas (e.g. receipt of material at the goods inwards area) are available to staff in the relevant area for reference as required – ADD 'training to the relevant procedures should be documented'.
Page 9: Approval of suppliers and customers	Approval of suppliers and customers- approval of customers is not a requirement of ISO 13485 or EU MDR, therefore procedures that document approval of customers would not be in-line with these documents
Page 10: Change control	"Changes should be formally approved by the relevant managerial representative of the areas of the operation impacted by the change prior to implementation" – ADD change should also be approved by management with responsibility for Quality.
Page 10: Change Control	"Changes should also be subjected to periodic review to ensure completion of actions which had been identified as required during the change control process." Is the review as part of Management Review sufficient?
Page 11: CAPA	"CAPAs should be subjected to regular review to ensure their full implementation and they should be subject to formal checks of their effectiveness." Is the review as part of Management Review sufficient?
Page 11: CAPA	"The requirement for a risk assessment to be considered should be documented on the deviation form." Risk assessment s not directly considered would impact assessment and investigation be sufficient.?
Page 11: Complaints	"All complaints, events or incidents received should be investigated and categorised into either a quality, technical/service, vigilance or distribution related complaint depending on the nature of the report". – determination of the complaint category is not described as the responsibility of the Distributor in the EU MDR / IVDR, the responsibility to determine quality and vigilance reporting is the responsibility of the manufacturer. SUGGEST that this is removed.
Page 12: Complaints	"The customer should be informed of the outcome of the complaint and all communications documented." Right now we allow the sales rep to judge the situation and confirm if they want to close in writing/verbally. This

	has helps customer relationships. Closure continues to be documented by BQ but not all closures with customers are done in writing. Will this be sufficient in the future?
Page 12: Key Personnel	"primary responsibility for ensuring that due care is met" – it is not clear what is met by this, clarification is needed. SUGGEST that it is changed to reflect responsibility for ensuring regulatory responsibilities are met.
Page 14: Records Management	"These records should be kept for up to 6 years following the date of receipt of the last batch/lot and may be requested by the HPRA" – retention period at 6 years is not documented in EU MDR/IVDR and should be recommendation, with clarification of life-time of device
Page 16: Traceability	Traceability system should be tested periodically – is a FSCA as detailed in page 23 (section 10) sufficient to demonstrate challenged?
Page 17: Temperature monitoring and mapping	NOTE: Confirms Medicinal product standards will be expected going forward "Although the document refers to medicinal products, the principles are the same for medical devices."
Page 17: FEFO	Expiry is not checked at goods in as it is checked before being dispatched from our other warehouses. FEFO is not in place in lean warehouses but a monthly report flags products approaching expiry and the electronic system will not release anything expired. Is this sufficient? SUGGEST rewording of the section to cover all scenario's.
Page 23: Medical Device Recalls	"The recall procedure should be regularly challenged (at least once per year) to ensure that the process is effective and capable of tracing all customers and medical devices in the event of a recall in a timely manner" – mock recall is not a requirement of the EU MDR/IVDR, it is agreed that this may be a good practice; SUGGEST that the wording be changed to make this a recommendation
Page 24: Transportation	Document reference is incorrect, document states 'Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medical devices and Active Substances' given the following statements that reference medicinal products, I believe that the title should be 'Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances'

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