British Dental Industry Association

- NB Update 2017

Martin Penver
Global Technical & Operations– Medical Directives
LRQA

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LRQA

Improving performance,
reducing risk

Agenda

- MDR Implementation
- OBL status from a Notified Body perspective

MDR Implementation

Proposal for a

- **REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC**

- 175 pages available final version requiring interpretation

Everyone will now interpret the text – but we have 3 years to implement

LRQA to apply end November 2017

MDR Implementation - interpretation

- Manufacturers of devices classified as class I, other than custom-made or investigational devices, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 17 after drawing up the technical documentation set out in Annex II. If the devices are placed on the market in sterile condition, are reusable surgical instruments or have a measuring function, the manufacturer shall apply the procedures set out in Annex VIII, Chapter I (Quality Management System) and Chapter III (Administrative provisions), or in Part A of Annex X. However, the involvement of the notified body shall be limited:
- (a) in the case of devices placed on the market in sterile condition, to the aspects concerned with establishing, securing and maintaining sterile conditions,
- (b) in the case of devices with a measuring function, to the aspects concerned with the conformity of the devices with the metrological requirements;
- (c) in the case of **reusable surgical instruments**, to the aspects related to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

  - ***A QMS & Full Technical file will be reviewed by a Notified Body – need to meet***

    "GENERAL SAFETY AND PERFORMANCE REQUIREMENTS Annex I (page 203)"

  - ***Note in MDD terms at the moment manufactures need a technical file but no QMS audit, and no NB involvement***

MDR Implementation - interpretation

CONFORMITY ASSESSMENT BASED ON *A* QUALITY *MANAGEMENT SYSTEM* AND *ON ASSESSMENT OF THE TECHNICAL DOCUMENTATION*

- The notified body shall randomly perform ***at least once every five years*** unannounced ***on-site audits*** to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment. The notified body shall establish a plan for the unannounced ***on-site audits*** which must not be disclosed to the manufacturer.

- 3 years for High Risk
- 5 years for low risk

- Generally accepted – cycle has started as from March 2017

What is in the recommendation that is different / new?

4.5. In the case of devices classified as class IIa or class IIb, the surveillance assessment shall also include assessment of the technical documentation in accordance with the provisions in Sections 5.3a to 5.3e of Chapter II of this Annex of the device(s) concerned on the basis of further representative sample(s) chosen in accordance with the rationale documented by the notified body in accordance with point (c) of Section 3.3.

No reference to the term STED or FULL

MDR - Key issues

Notified Bodies

- Strengthened criteria in relation to surveillance audits of manufacturers
- **Sample and test devices** and technical documentations, **during audits**, according to pre-defined sampling criteria and testing procedures to ensure that the manufacturer continuously applies the approved Quality Management System
- Material reconciliation of stock
- Procedure in place for manufacturer to update PSURs as per Article 60c
- Joint audit & designation
- Role in vigilance & market surveillance
- Unannounced inspections (3 & 5 year cycle).

Virtual Manufacturing
status from a Notified Body perspective

- Redesignation of LRQA against MDD in Feb 2016 saw a strong focus on OBL / Virtual Manufacturing reviews.

- Major NC raised against LRQA
  - A number of major deficiencies were identified which the reviewer categorised as minor deficiencies. E.g. total absence of sterilisation and shelf life validations, biocompatibility reports and a lack of clinical evaluation data for the sterile OBL product. No justification was given for this categorisation within the reviewers report.
    - ❖ The review met the MHRA guidance of a STED
  - Other NC's related to not completing a full technical file review (OBL).

The requirement is already expected to be Implemented by the commission and therefore any Guidance can only focus on expectations

OBL status from a Notified Body perspective – LRQA Letter

- LRQA must therefore now inform all Virtual Manufacturing clients that they will be given 6 months from the 1st of June 2016 to ensure they hold the full technical documentation.

- Very limited proprietary information contained in the Original Equipment Manufacturers (OEM) technical documentation may be redacted from OBL technical documentation, provided full access to the OEM's technical documentation is given to LRQA during technical file review. This should be provided at the start of the scheduled review.

- The following guidance documents may assist clients
  - NB-MED/2.5.1/Rec5 Technical Documentation

DO-NOT wait for MHRA published guidance – compliance is NOW – informed All in BDIA 2016

Acceptable Proprietary information examples :-

a) The OEM has a critical process which can-not be shared with the virtual manufacturer. However the testing reports of the finished product demonstrate safety and performance. The OEM provides access of the proprietary information to the virtual manufacturers Notified Body (LRQA) who can verify that the test reports cover the critical process.

b) The OEM has a critical formulation for the raw material for a device, they are willing to share the chemical analysis of the finished material and the biocompatibility reports completed by an independent test house, but not the full details with the Virtual Manufacturer.

c) The OEM has a specific formulation for the composition for the device and they are not willing to share the chemical analysis of the finished material, or the biocompatibility reports, or sensitive test data. Here the virtual manufacturer completes their own chemical analysis and biocompatibility testing (by an independent test house) to demonstrate safety and performance of the finished device which they are placing on the market.

Notes on Proprietary information examples

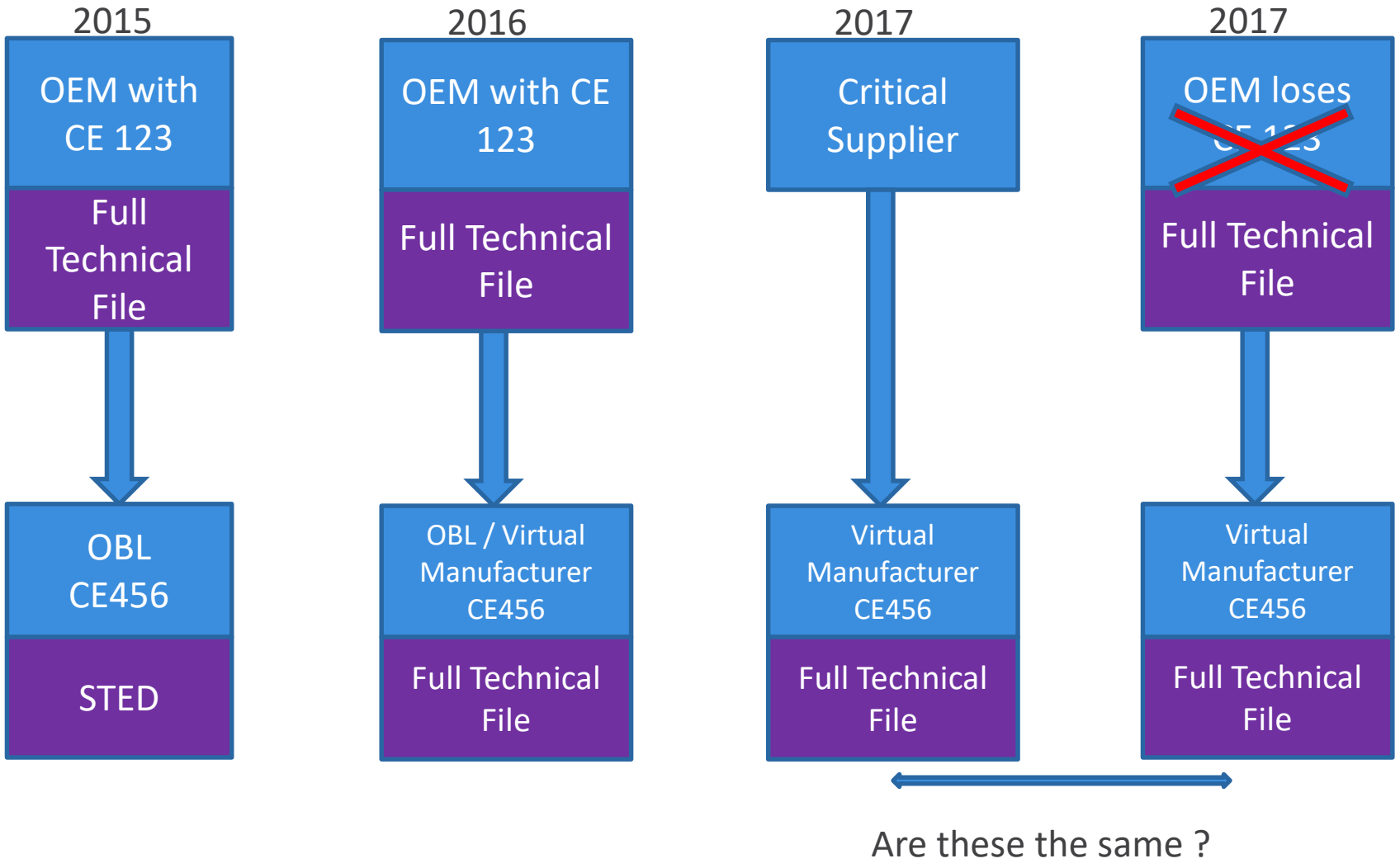
- The important criteria on proprietary information is that a contract between the OEM and the virtual manufacturer ensures that any changes in formulation ratios, processing or ingredients are communicated, and that this information is shared with LRQA as additional reviews may be required.

- The design process may remain proprietary to the OEM, but the final specification needs to be within the Virtual manufacturers technical file and therefore reviewed by LRQA.

- Where the OEM sells various brand named products to several virtual manufactures, and does not wish to share the clinical evaluation, the virtual manufacture will need to perform their own clinical evaluation and evaluate post market data on similar devices placed on the market to ensure they can determine the safety and performance of the device, they intend to place on the market. This option does not remove the expected responsibility of the OEM to inform the virtual manufacturer of recalls for their device or other branded devices, that affect the safety and performance data. (this requirement must be detailed in the contract).

- If OEM supplies documentation directly to LRQA, then it must be in English.

Un-answered question



Un-answered question - Are these the same ?

From a Notified Body auditing the Virtual Manufacturer what is the risk ?

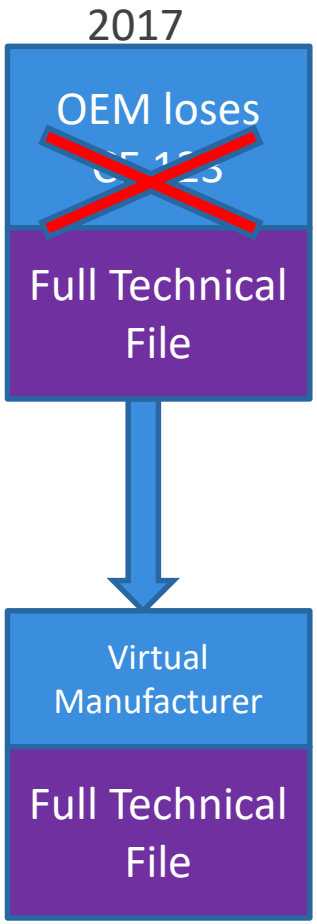
Has the OEM – Critical supplier decided not to CE mark ?

Has CE123 decided not to issue a certificate ? WHY?

How can the Notified Body – check and validate the reason?

The Virtual Manufacturer

- Holds the Full Technical File
- Has QMS & UV visits from the NB
- controls their critical suppliers through ISO13485
- Gathers and reports vigilance



New LRQA procedure for Assessment

- **The OBL must hold technical documentation for each device**, and the auditor will need to agree a plan of when these files will be available for review by LRQA. If there are a large quantity of OBL devices, a sampling plan will be required (see Below) and LRQA should take a

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risk based approach on which files should be reviewed first. The auditor should record within the Surveillance audit report what the timescale and plan has been agreed with the client.

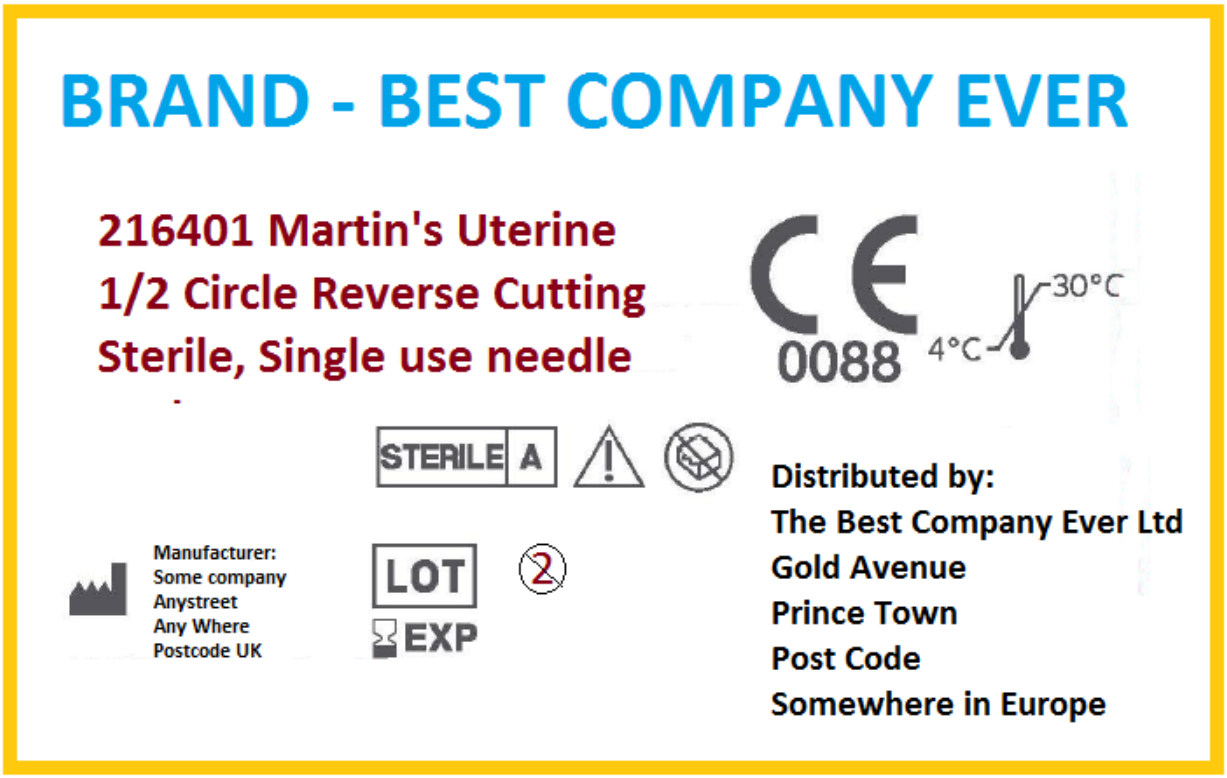
- **The management process will need to consider the requirements for Unannounced audits at their premises and /or at the OEM premises, and a revised contract covering this with the OEM must be in place.**

Clearly indicate if any areas that require specific expertise (activity codes) are selected for the next visit.

Technical Review of QMS Surveillance visit - same as overall Assessment Methodology , PCENMDD3510A03

Still an option

- Why are you an OBL? Why not a distributor ?



- No NB costs & no un-announce visits and no new regulation

Question Time

- Now is the time to list your questions

Martin Penver

Head of Notified Body
T + 44 (0)330 414 1244
E medicaldirectives@lrqa.com

LRQA – UK
1 Trinity Park, Bickenhill Lane,
Birmingham, B37 7ES
UK.

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