Impact of MD/IVD EU regulations on IT systems and in-house testing methods

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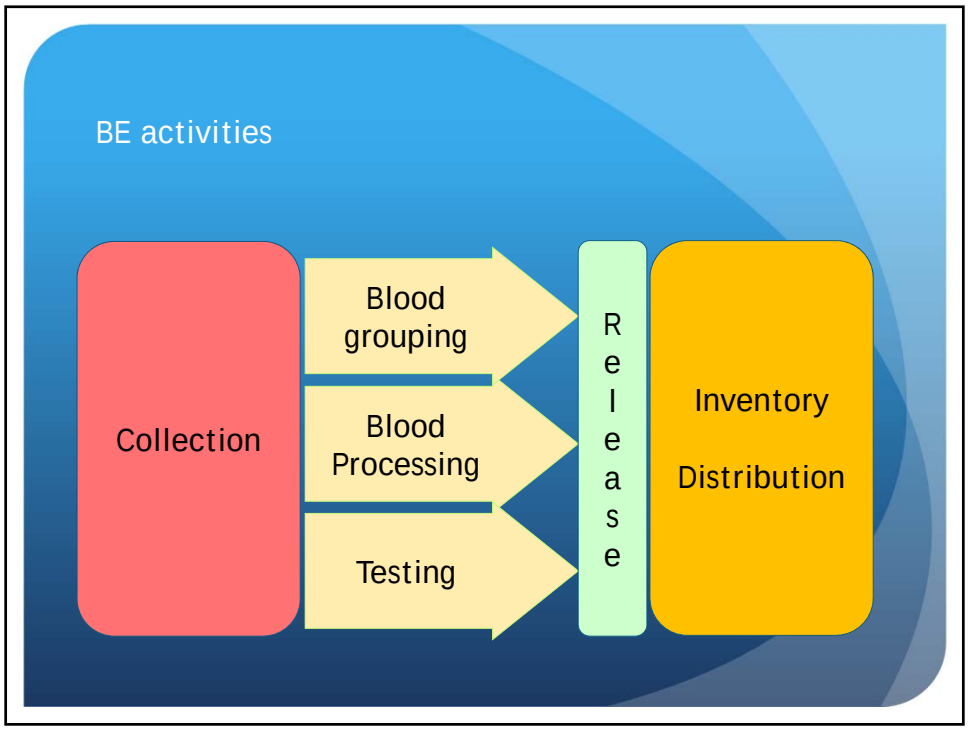
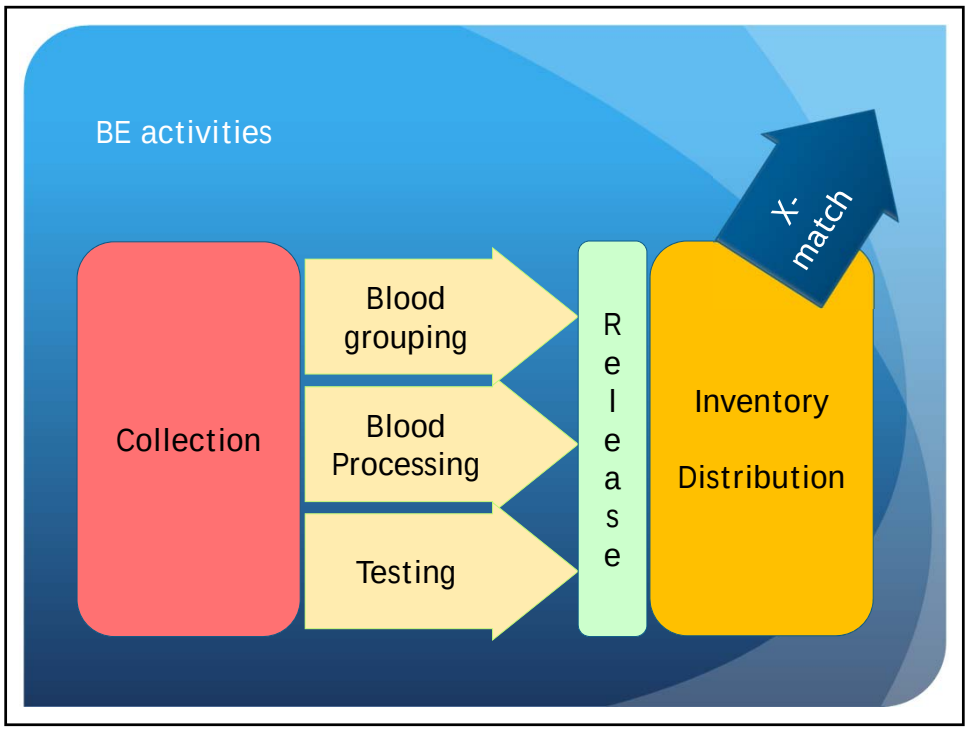
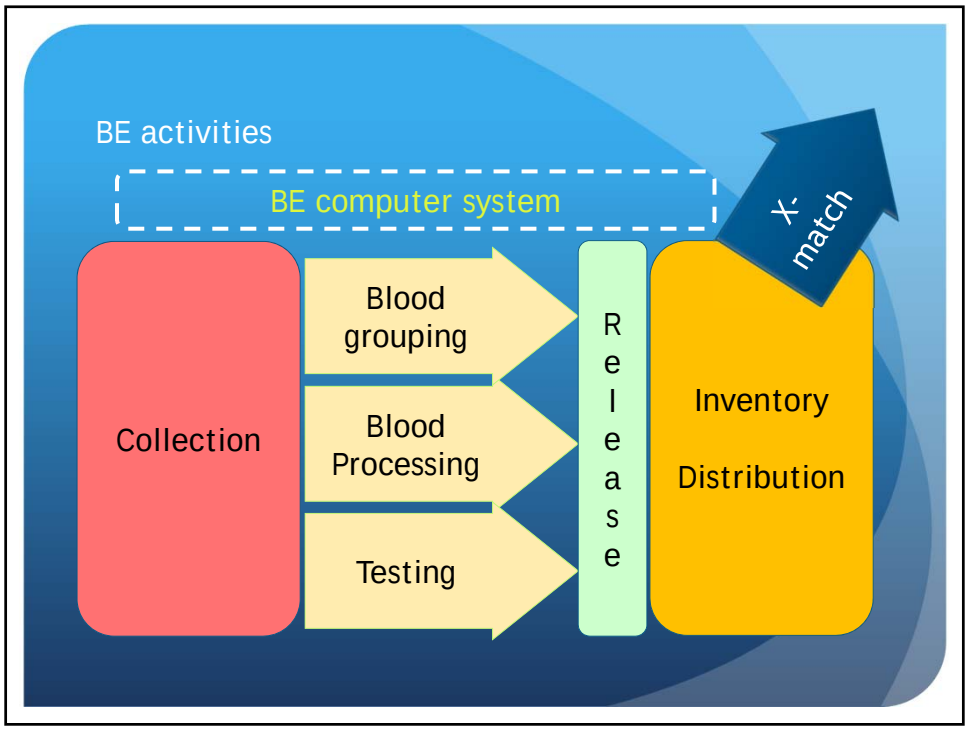
Disclaimer

I am a physician, not a lawyer or affiliated with a regulatory body, so the interpretations of the EU regulations are from that point of view


BE activities
Collection
Blood grouping
Blood Processing
Testing
Release
Inventory
Distribution


BE activities
X-match
Collection
Blood grouping
Blood Processing
Testing
Release
Inventory
Distribution



EU regulations

MDR 2017/245

5.5.2017 EN Official Journal of the European Union L 117/1

I

(Legislative acts)

REGULATIONS

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

IVDR 2017/246

L 117/176 EN Official Journal of the European Union 5.5.2017

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 April 2017
on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

(Text with EEA relevance)

EU regulations - replacing

MDR 2017/245

- Council Directive 93/42/EEC (MD)

IVDR 2017/246

- EU Directive 98/79/EC (IVD)

EU regulations – what's new

MDR 2017/245

- Stand alone software is now a medical device

IVDR 2017/246

- In-house methods/reagents are no longer exempt

Terms used

Notified body

Medical device coordination group (MDCG)

Common specifications (CS)

Blood establishment computer system (BECS)

Definitions (MDR, Article 2)

'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

– diagnosis, prevention , monitoring, prediction, prognosis, treatment or alleviation of disease

Blood establishment computer system (BECS)

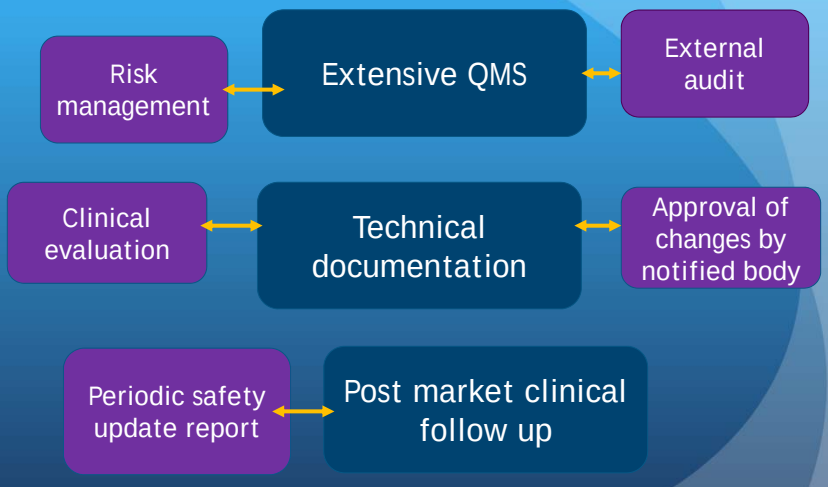
Classification (Annex VIII, rule 11)

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have impact that may cause:

– death or an irreversible deterioration of a person's state of health, in which case it is classified as class III

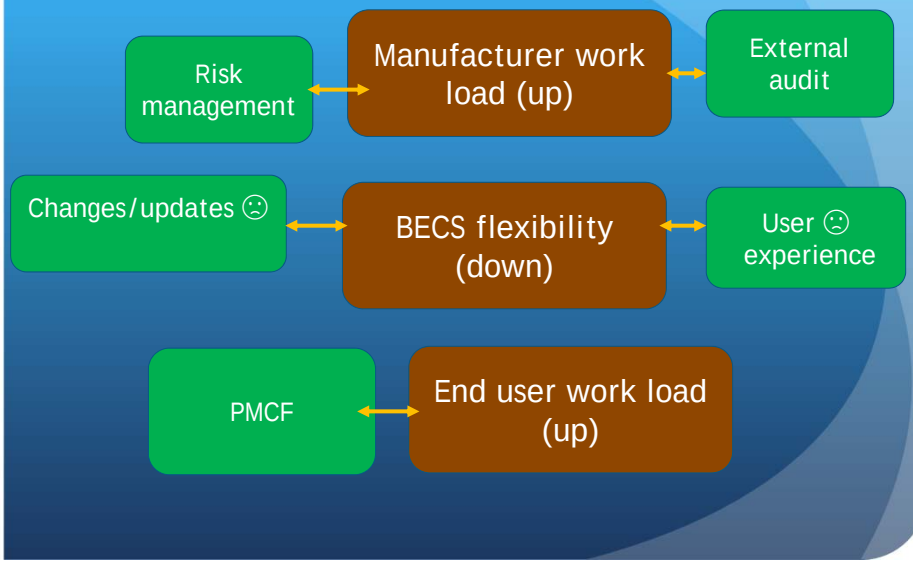
– a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb

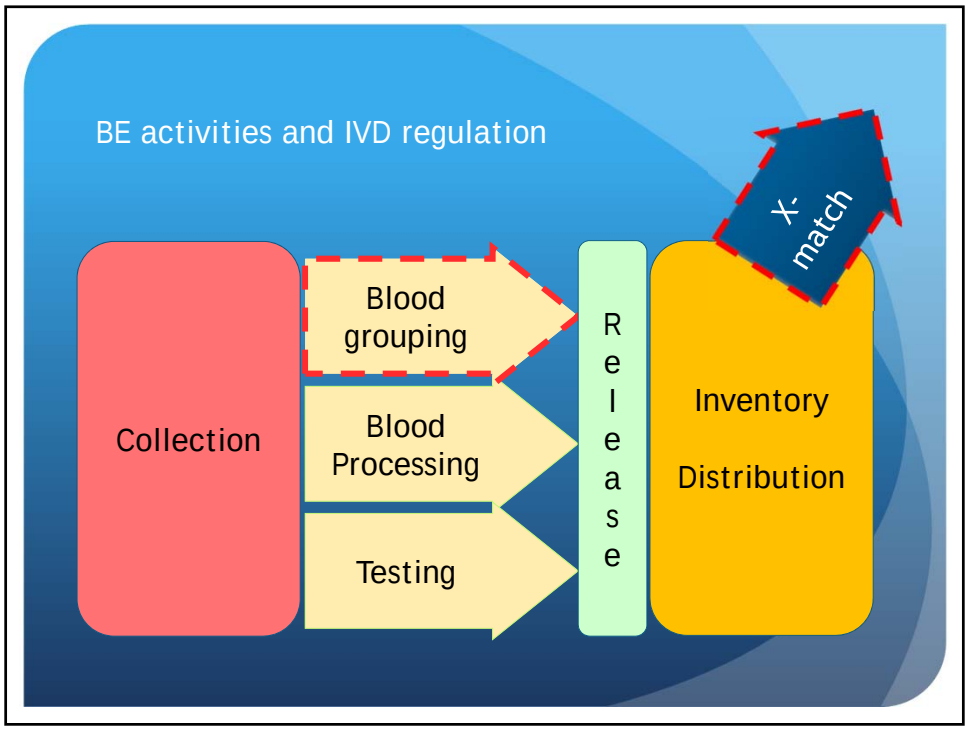
Implications of MDR for BECS manufacturer

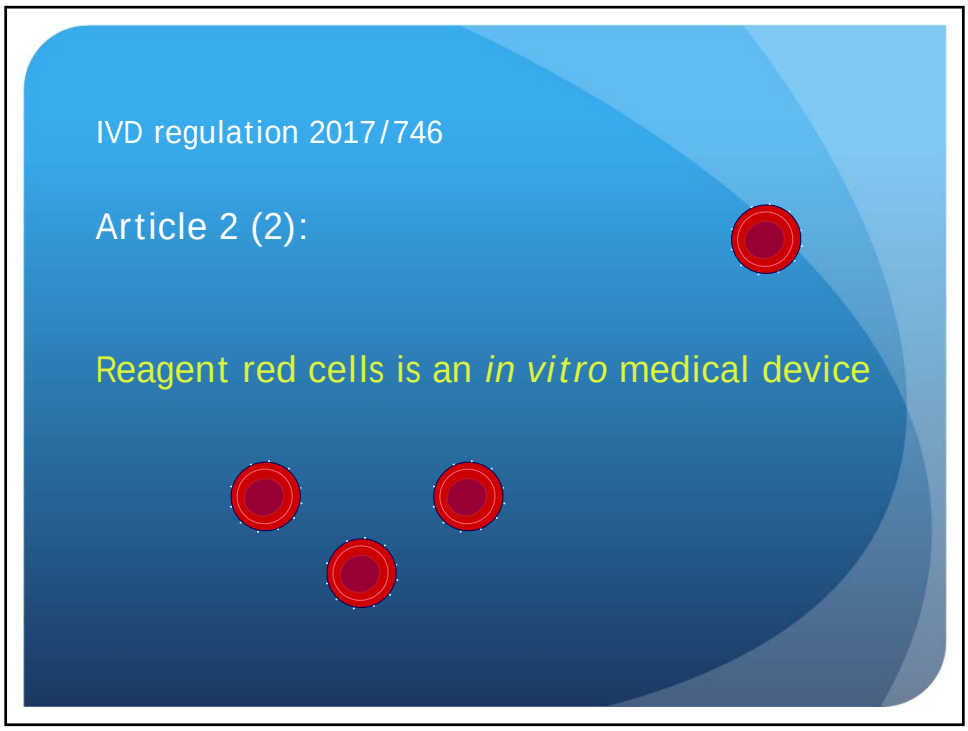


Expected consequences

Expected consequences




BE activities and IVD regulation
X-match
Collection
Blood grouping
Blood Processing
Testing
Release
Inventory
Distribution


IVD regulation 2017/746
Article 2 (2):
Reagent red cells is an *in vitro* medical device

Classification

ANNEX VIII, Rule 2

Devices to be used for blood grouping…..are classified as class C, except when intended to determine any of the following markers:

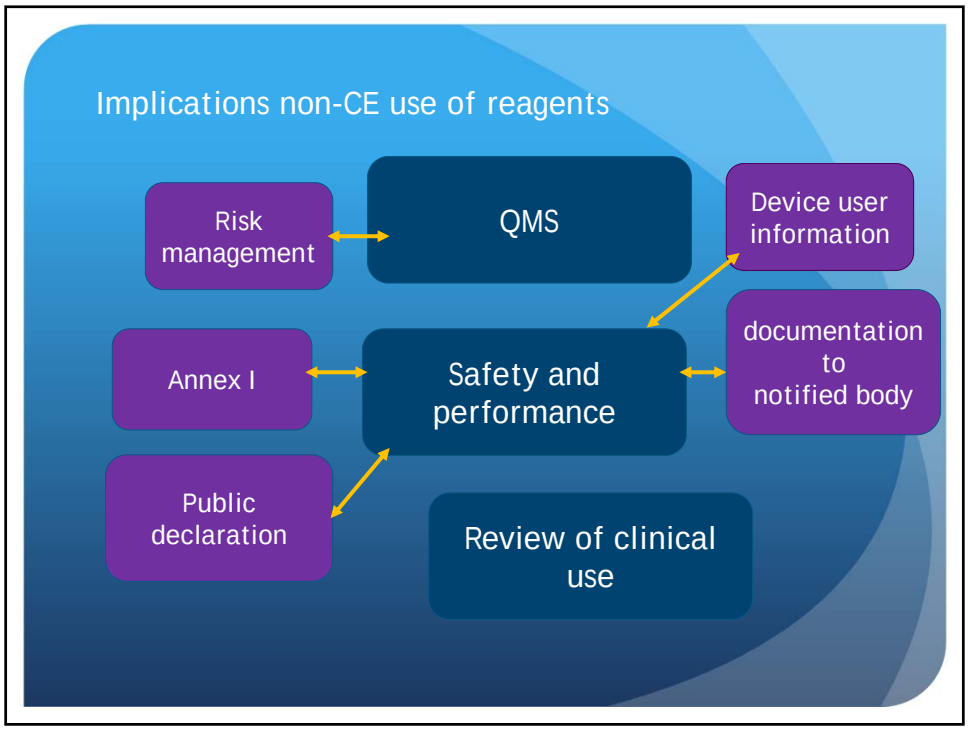
- ABO system
- Rhesus system
- Kell system
- Kidd system
- Duffy system

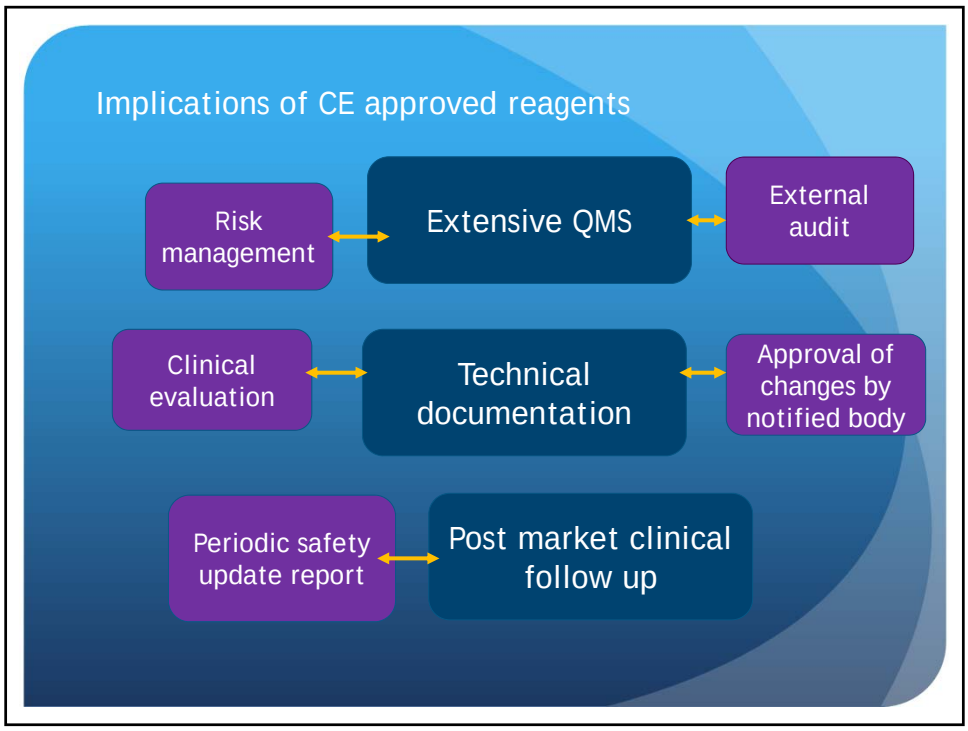
In which case they are classified as class D

CE-exception for health institutions

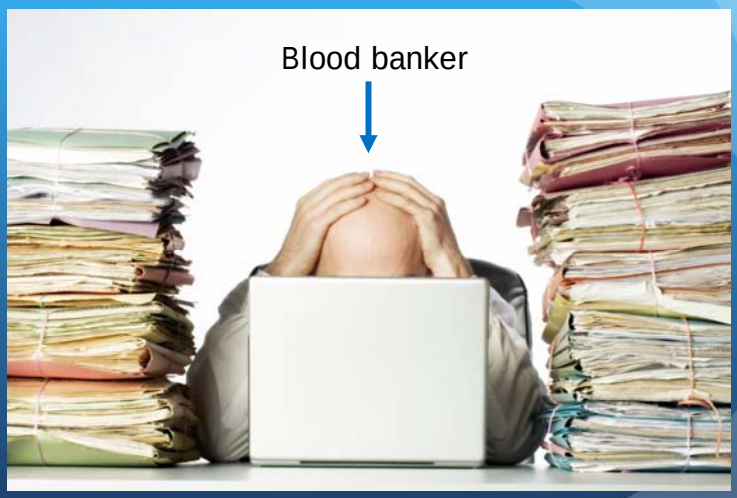
Article 5 (5)

1. Not transferred to other legal entity
2. Appropriate QMS
3. Compliance with EN ISO 15189
4. Justification for use of not CE-approved reagent
5. ….8.


Implications non-CE use of reagents
Risk management
QMS
Device user information
Annex I
Safety and performance
documentation to notified body
Public declaration
Review of clinical use


Implications of CE approved reagents
Risk management
Extensive QMS
External audit
Clinical evaluation
Technical documentation
Approval of changes by notified body
Periodic safety update report
Post market clinical follow up

Expected consequences



Pending questions

- Does a BECS as a whole or only certain modules thereof constitute a medical device?
- Common specifications?
- Capacity of notified body