DITTA

European Commission

GMTA Global Medical Technology Alliance

EU Medical Devices Regulation – extension of the transition period explained

Tuesday 26th September, 16:30 – 17:30 CEST
InterContinental, Berlin (IMDRF meeting venue)

Coordinated by MedTech Europe from diagnosis to cure COCIR

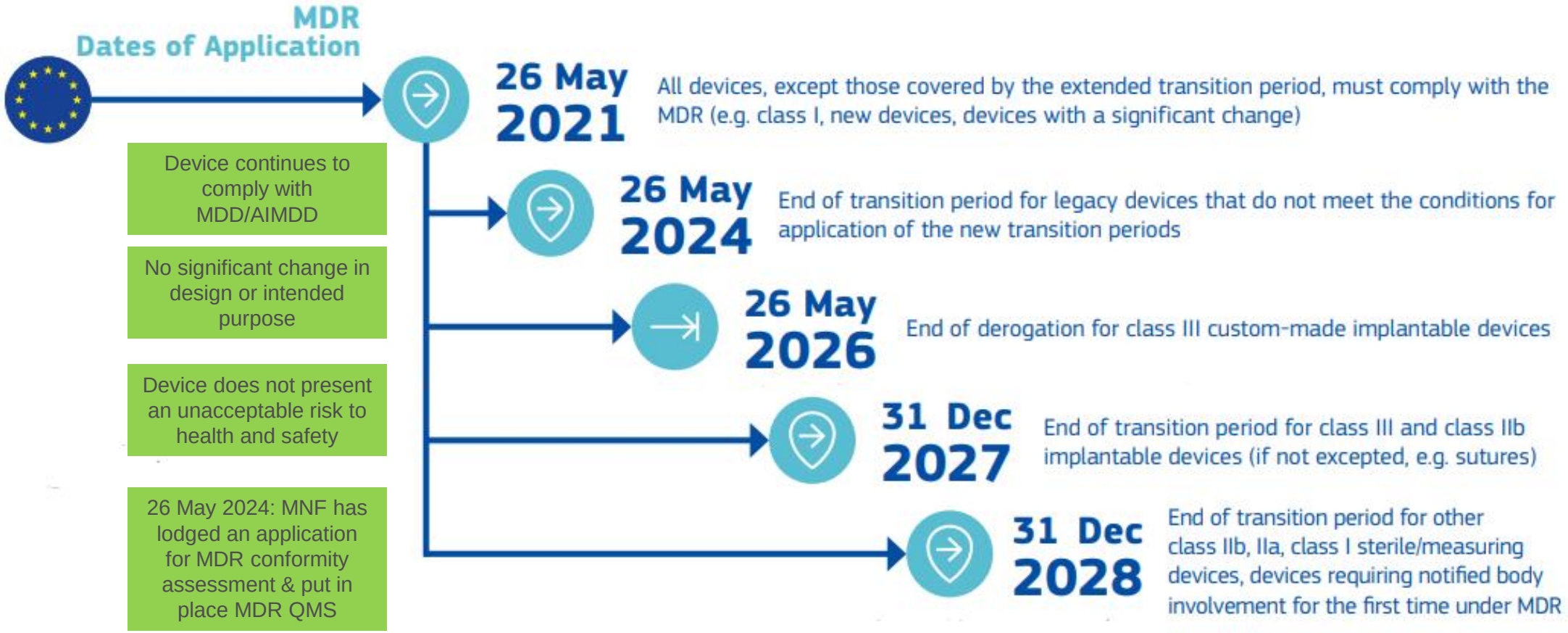
MDR - extension of the transition period

- Drivers and objectives
  - challenging transition from MDD/AIMDD to MDR
  - avoid risk of shortages of medical devices
  - ensure patient access to wide range of safe and performant devices
  - give more time to manufacturers and to notified bodies to complete MDR conformity assessment
  - no lowering of quality or safety requirements

MDR - extension of the transition period

- Main elements
  - staggered extension of MDR transitional period depending on risk class
  - conditions for extension
  - ‘appropriate surveillance’ by notified bodies during transitional period
  - extension of validity of certificates issued under (AI)MDD
    - including expired certificates under certain conditions
  - derogation for class III custom-made implantable devices
  - removal of ‘sell-off' dates in MDR and IVDR

MDR – extension of transition period



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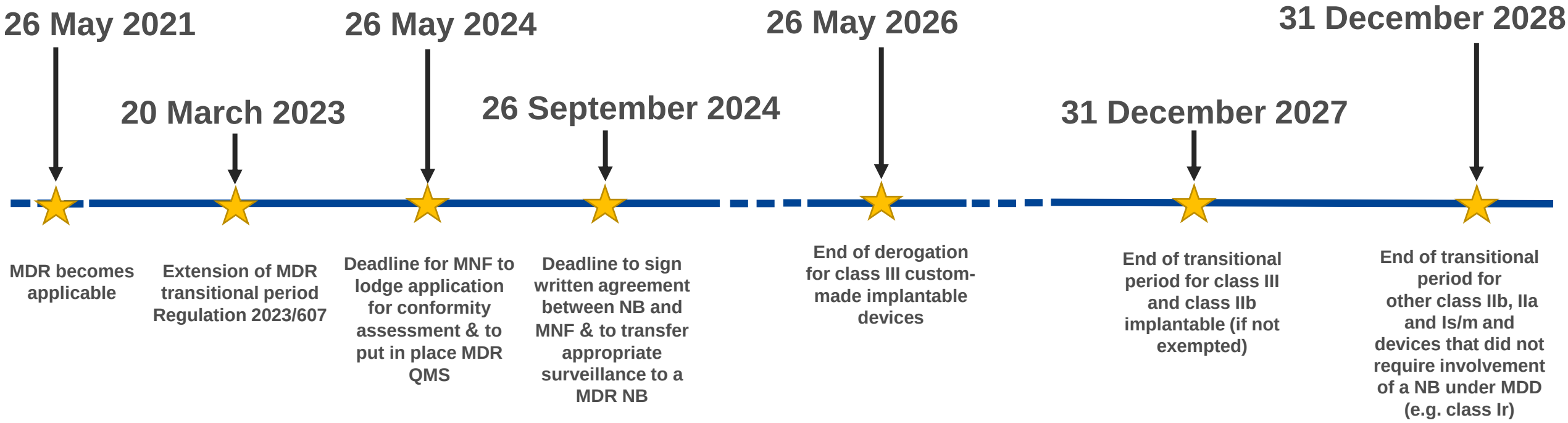
MDR – extension of transition period



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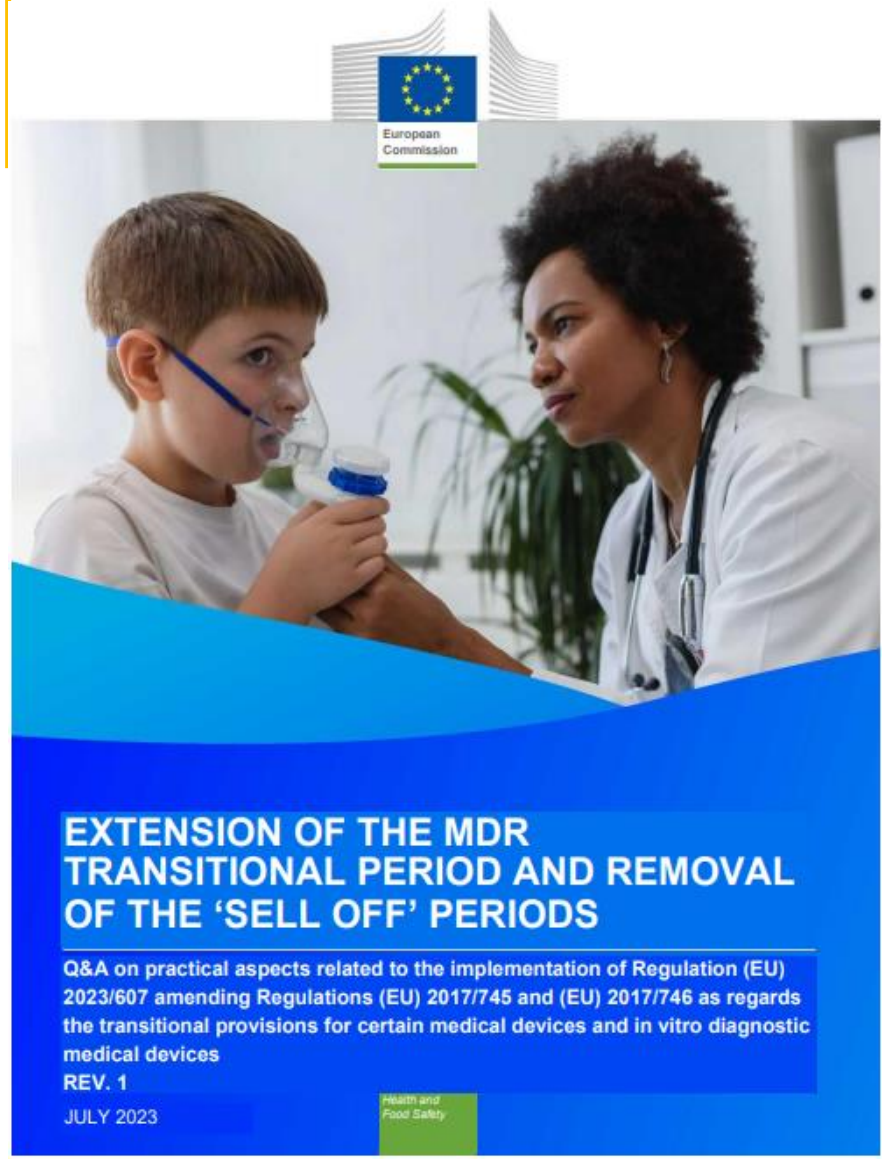
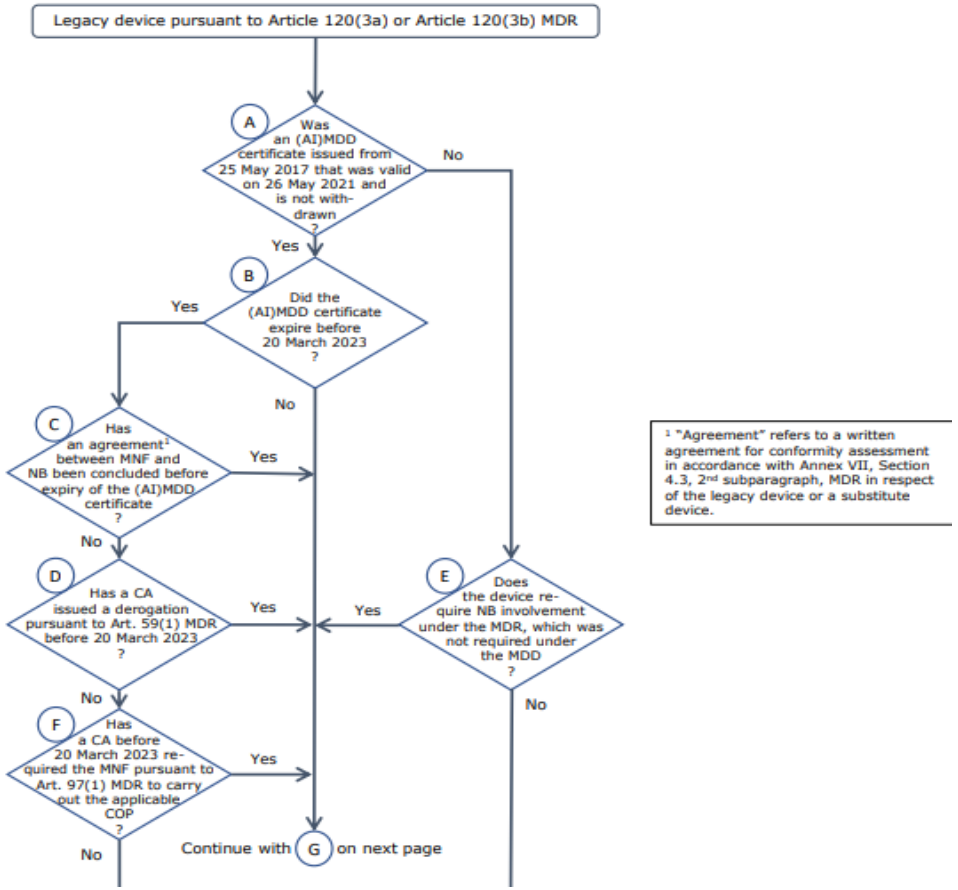


[mdr_proposal_extension-q-n-a.pdf (europa.eu)]

Flowchart
(Rev. 1)

Conditions and deadlines for placing 'legacy devices' and class III custom-made implantable devices on the market or putting them into service in accordance with Article 120 MDR, as amended by Regulation 2023/607



[md_devices-art120_flowchart_0.pdf (europa.eu)]

Thank you

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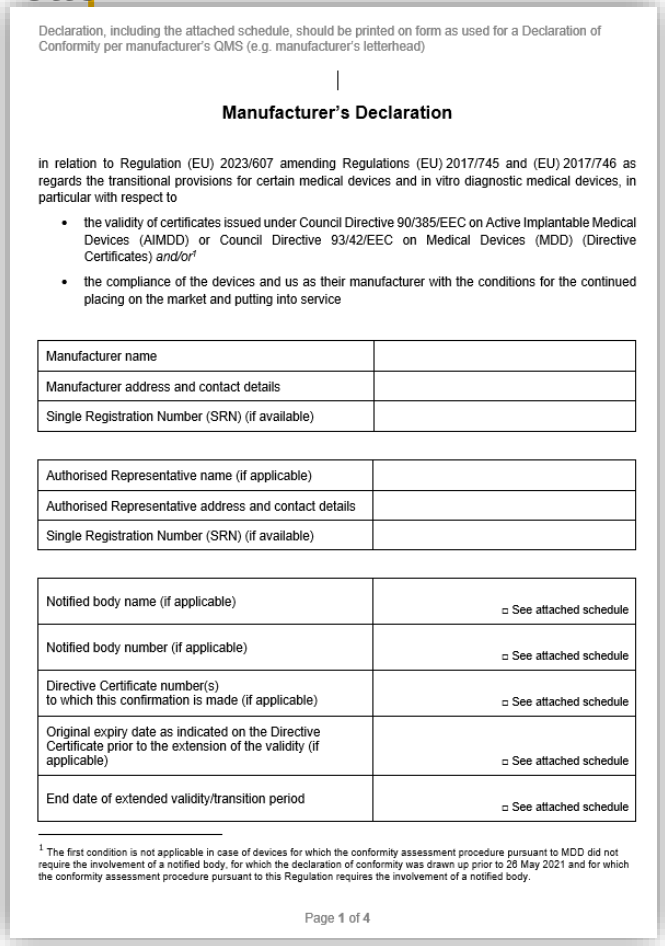
Implementation of (EU) 2023/607 – Manufacturer Declaration and Notified Body Confirmation Letter



Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	
Manufacturer address and contact details	
Single Registration Number (SRN) (if available)	

Authorised Representative name (if applicable)	
Authorised Representative address and contact details	
Single Registration Number (SRN) (if available)	

Notified body name (if applicable)	☐ See attached schedule
Notified body number (if applicable)	☐ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☐ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☐ See attached schedule
End date of extended validity/transition period	☐ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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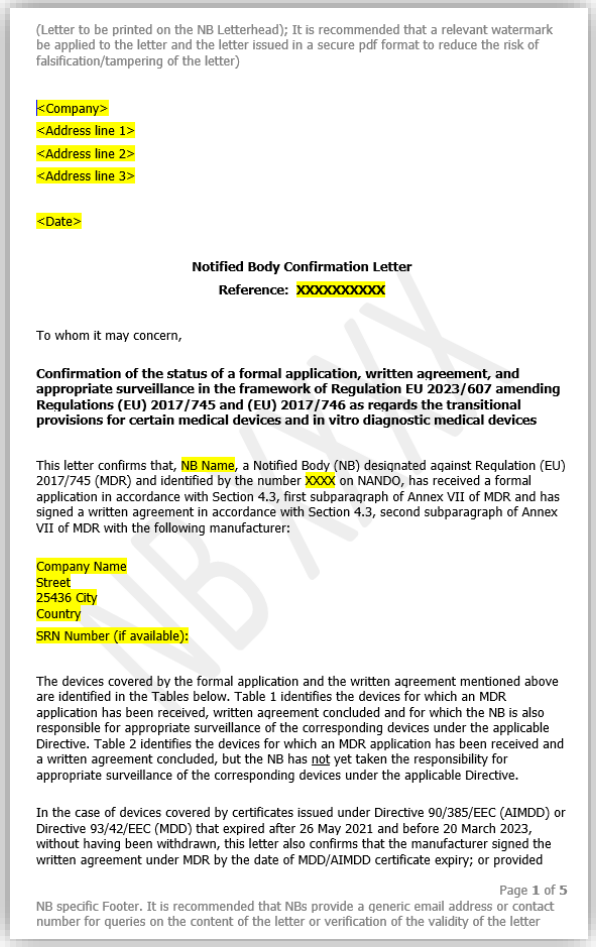
Harmonised template for Manufacturer self-declaration of compliance to EU 2023/607; also identifies:

- the devices subject to the declaration,
- the applicable transition periods



(Letter to be printed on the NB Letterhead); It is recommended that a relevant watermark be applied to the letter and the letter issued in a secure pdf format to reduce the risk of falsification/tampering of the letter)

<Company>
<Address line 1>
<Address line 2>
<Address line 3>

<Date>

Notified Body Confirmation Letter
Reference: XXXXXXXXXX

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, NB Name, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number XXXX on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Company Name
Street
25436 City
Country
SRN Number (if available):

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided

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NB specific Footer. It is recommended that NBs provide a generic email address or contact number for queries on the content of the letter or verification of the validity of the letter

Notified Body confirmation letter identifies:

- devices under MDR application, corresponding Directive certificate references
- if the MDR NB is responsible for appropriate surveillance of the corresponding directive certificates or

NB confirmation letter is only issued for devices for which the MDR application and written agreement (contract) have been concluded within the applicable deadlines

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

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Manufacturer perspective

Philippe Lartigue
GE HealthCare - Sr Director RA Global Policy

European Commission

MDR - Extended transition period

Effect for Manufacturers and devices:

- can continue to place on MDD legacy devices on EU market until end of 2027/2028 (according to Risk Class)
- reinforced conditions to be met
- High level of surveillance of legacy devices:
  - PMS requirements of the MDR applicable to legacy devices from 26 May 2021
  - No unacceptable risk
  - Surveillance of legacy device transferred to the Notified Body in charge of the MDR certification

Deadlines for benefiting from the extended transitions:

- 26 May 2024: lodge an application for MDR certification of the device or its substitute, comply with MDR QMS requirements
- 26 September 2024: sign agreement with Notified Body for the application and transfer surveillance

Validity of EC MDD/AIMDD certificates extended but no update of the document (incl. original expiry date)

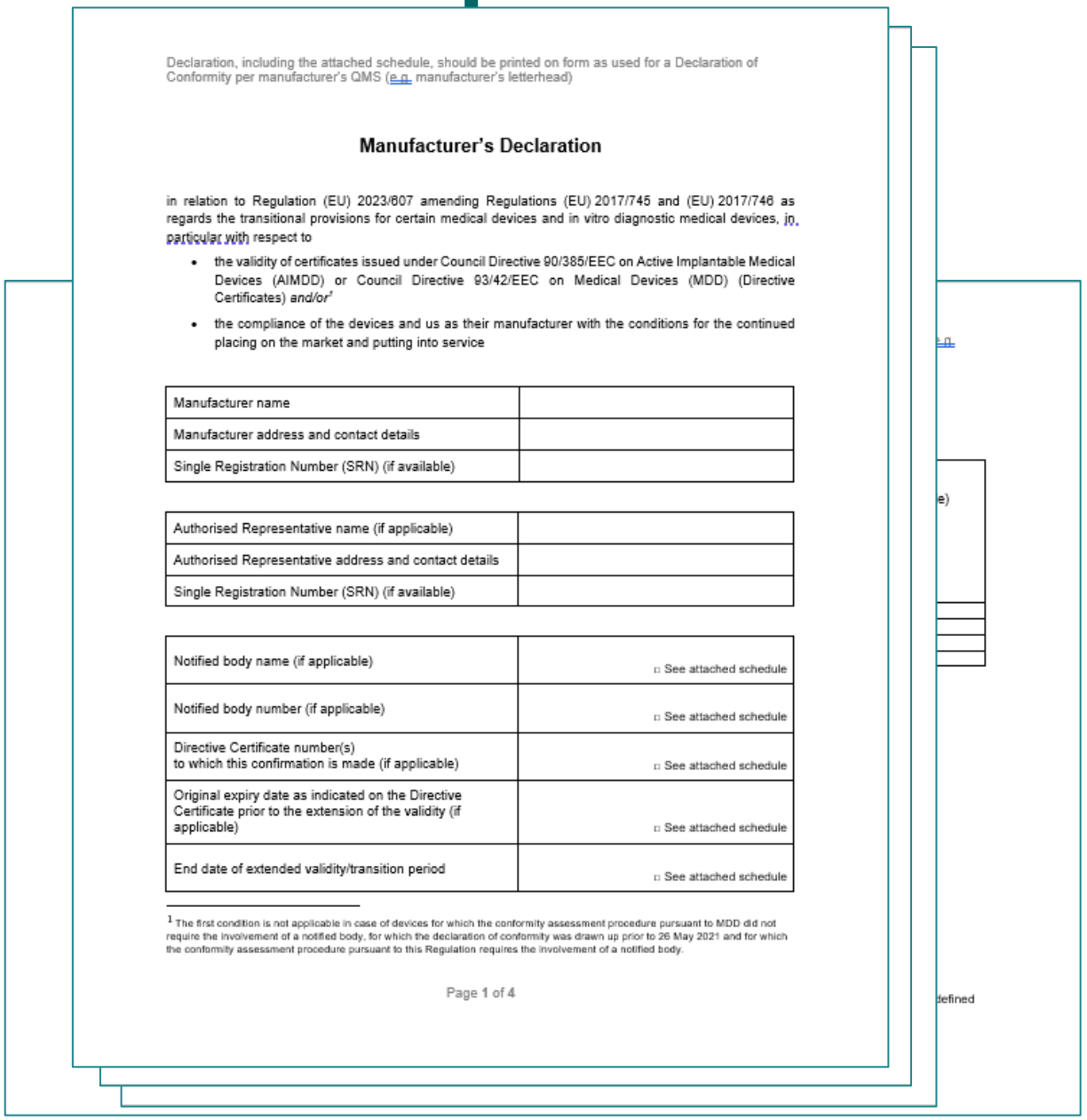
- Possible challenges and questions -Need communication and explanation
- EU Q&A, templates and factsheet for non-EU authorities
  are available on EU Commission website

European Commission

MDR - Extended transition period

Documents confirming that the conditions of the extended period are fulfilled:

- **Manufacturer's Declaration:**
  - Harmonized template (see EU Q&A)
  - Provides all details on MDD legacy devices, Certificates, MDR Notified Body, substitute devices, validity date, ..
- **Notified Body Confirmation Letter:**
  - Common template (see EU Q&A)
  - List of devices covered by the extension
- **Free Sale Certificate:**
  - May be issued by National Competent Authorities



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MDR - Extended transition period

The MDR amendment answered the challenges of MDD/AIMDD to MDR transition and associated risk of shortages of medical devices

- Longer transition for legacy devices
- Welcome the rapid development of tools to support the amendment: EU Q&A, Factsheets, Templates for Manufacturers and Notified Bodies, ..

Remaining challenges:

- Validity of Certificates extended without changing the expiry date on the document:
  Tools are available for showing conformity to customers and EU or non-EU authorities
- Get acceptance of the existing templates by non-EU authorities, avoid the request of redundant documents
- Maintain harmonized application of the transition period in all EU countries and by all stakeholders
- Free Sale Certificates: need an implementing act with common and electronic format of the FSC

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