Personalized Medical Devices
Working Group Update

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NWIP Purpose

- Develop an IMDRF Technical Document that provides recommendations supporting a harmonized approach to defining medical devices that are manufactured for a particular individual.

Rationale

- Technology has progressed to where it is now possible to ‘mass produce’ individualized medical devices:
  - e.g. 3D printing of devices based on patient CT Scan data.
- Original GHTF documentation does not adequately address these types of devices.
Progress

- Conducted public consultation on draft definitions document, Apr-May 2018.
- Held a face to face meeting in Seoul to incorporate comments, Jun 2018 (thank you to Korea MFDS).
- Submitted to MC for consideration at September meeting:
  - Final draft definitions document
  - New work item extension to develop recommendations for regulatory pathways.
Key Feedback Themes from Consultation

Improve the examples

• e.g. - The examples are helpful but would be more useful if additional text were provided to explain why one example meets one definition instead of another, particularly between the custom-made and patient-specific devices.

Confusion over the term ‘industrial manufacturing process’

• e.g. - Is there a chance for IMDRF to provide a common understanding of “industrial manufacturing process”? 
Key changes following consultation

• Explanatory text added to each example to better illustrate relevant concepts for each device category

• Removed the term ‘industrial manufacturing process’ from the note under custom-made

• Removed the term, ‘patient-specific’ from the document in favor of ‘patient-matched;’ as ‘patient-specific’ could be misconstrued as ‘custom-made,’ whereas ‘patient-matched’ is more descriptive of the devices in this category
Key changes following consultation

• Added a section of supporting definitions:
  – batch
  – DICOM files
  – homogenous batch
  – mass-produced medical device
  – specific design characteristics
  – specified design envelope
Proposed Definitions

• personalized medical device – a generic term to describe any of the types of medical devices that are intended for a particular individual, which could be either a custom-made, patient-matched, or adaptable medical device.
Proposed Definitions

custom-made medical device – a medical device that, at a minimum, meets the following requirements:

• it is intended for the sole use of a particular individual (which could be a patient or healthcare professional); and

• it is specifically made in accordance with a written request of an authorized healthcare professional, which gives, under their responsibility, specific design characteristics; even though the design may be developed in consultation with a manufacturer; and

• it is intended to address the specific anatomo-physiological features or pathological condition of the individual for whom it is intended.
 Proposed Definitions

custom-made (continued)

Note 1: Medical devices that are patient-matched, adaptable or mass-produced shall not be considered to be custom-made

Note 2: A custom made device is intended for a case where an individual’s specific needs cannot be met, or cannot be met at the appropriate level of performance, by an alternative device available on the market.
Proposed Definitions

**patient-matched medical device** – a medical device that meets the following requirements:

- it is matched to a patient’s anatomy within a specified design envelope using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging; and

- it is typically produced in a batch through a process that is capable of being validated and reproduced; and

- it is designed and produced under the responsibility of a manufacturer even though the design may be developed in consultation with an authorized healthcare professional.
Proposed Definitions

patient-matched (continued)

Note 1: A written request from an authorized healthcare professional may be present; but is not mandatory.

Note 2: The number and type of design inputs in consultation with a healthcare professional may vary depending on the medical devices to be manufactured.

Note 3: The design must remain within the validated parameters of the specified design envelope.
Proposed Definitions

**adaptable medical device** – a medical device that meets the following requirements:

- it is mass-produced; and
- it is adapted, adjusted, assembled or shaped at the point of care, in accordance with the manufacturer’s validated instructions, to suit an individual patient’s specific anatomo-physiologic features prior to use.
Proposed Annex

Examples of each personalized medical device category:

• custom-made medical devices,
• patient-specific medical devices,
• adaptable medical devices.
Next Steps

- **Sept 2018**: MC Face to Face Meeting
- **Oct-Dec 2018**: WG Teleconferences
- **Jan 2019**: Develop Draft
- **Apr 2019**: MC Teleconference
- **Jun 2019**: Approve Draft for Public Consultation

- **MC**
  - Face to Face Meeting
  - Approve Final Draft Definitions & NWIE for Regulatory Pathway Recommendations

- **WG**
  - Teleconferences
  - Incorporate comments (Location TBD)

- **MC**
  - Teleconference
  - Approve Final Draft Regulatory Pathways
Thank You