eAF DES Change Summary

Summary of DES changes applied to v.1.25.0.0

An agency of the European Union

Purpose

The aim of this document is to summarise the changes applied to the Data Exchange Standard covering variation and human forms for version 1.25.0.0 of the Electronic Application Forms.

It should be noted this document in no way replaces the current DES documents for each of the respective forms.

In all instances, and to facilitate understanding, an extract of the original schema definition is supplied, along with the updated version.

To enable cross reference to the release notes for 1.25.0.0, this document will reference the corresponding Change Request/defect reference number associated with the DES change.

Change Requests

1. SD-403901
2. SD-121617
3. SD-179089

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For SD-403901

a. For HUMAN
maa_human_XSD changes:

(This is part of maa_human)

Original:

```xml
<xs:element name="Manufacturer-device">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="Manu-device-checkbox" type="rdm:yes-no"/>
      <xs:element name="Manu-device-Yes-No" type="rdm:yes-no"/>
      <xs:element name="Manufacture-contact-details" type="rdm:contact-details
type" minOccurs="1" maxOccurs="unbounded"/>
      <xs:element name="CE-mark" type="rdm:yes-no"/>
      <xs:element name="Device-identification" minOccurs="0" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="Device-name" type="xs:string"/>
            <xs:element name="Device-description" type="xs:string"/>
            <xs:element name="Device-serial-no" type="xs:string"/>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
      <xs:element name="Notified-body">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="Add-certificates" type="rdm:yes-no"/>
            <xs:element name="Contact-details" minOccurs="1" maxOccurs="unbounded">
              <xs:complexType>
                <xs:complexContent>
                  <xs:extension base="rdm:contact-details-type">
                    <xs:sequence>
                      <xs:element name="Name" type="xs:string"/>
                      <xs:element name="Number" type="xs:string"/>
                    </xs:sequence>
                  </xs:extension>
                </xs:complexContent>
              </xs:complexType>
            </xs:element>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

Changed to:

```xml
<xs:element name="Medical-devices">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="Med-devices-checkboxes" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="Med-devices-checkbox-a" type="rdm:yes-no"/>
```

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```xml
<xs:element name="Med-devices-subSections-a" maxOccurs="unbounded">
    <xs:complexType>
        <xs:sequence>
            <!-- 2.2.4.1 -->
            <xs:element name="Device-name" type="xs:string"/>
            <xs:element name="Device-description" type="xs:string"/>
            <xs:element name="Device-purpose" type="xs:string"/>
            <xs:element name="Device-classification" type="rdm:radiobutton"/>
            <xs:element name="Device-serial-no" type="xs:string"/>
            <xs:element name="sterile" type="rdm:yes-no"/>
            <xs:element name="measuring_function" type="rdm:yes-no"/>
            <xs:element name="reusable" type="rdm:yes-no"/>
            <!-- 2.2.4.2 -->
            <xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
            <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>
            <!-- 2.2.4.3 -->
            <xs:element name="confirm-compliance" type="rdm:yes-no"/>
            <xs:element name="explain-no" type="xs:string"/>
            <xs:element name="specify-yes" type="rdm:radiobutton"/>
            <!-- 2.2.4.4 -->
            <xs:element name="Contact-details">
                <xs:complexType>
                    <xs:complexContent>
                        <xs:extension base="rdm:contact-details-type">
                            <xs:sequence>
                                <xs:element name="Telephone" type="xs:string"/>
                                xs:element name="Email" type="xs:string"/>
                                <xs:element name="Number" type="xs:string"/>
                            </xs:sequence>
                        </xs:extension>
                    </xs:complexContent>
                </xs:complexType>
            </xs:element>
        </xs:sequence>
    </xs:complexType>
</xs:element>
<xs:element name="Med-devices-checkbox-b" type="rdm:yes-no"/>
<xs:element name="Med-devices-subSections-b" maxOccurs="unbounded">
    <xs:complexType>
        <xs:sequence>
            <!-- 2.2.4.1 -->
            <xs:element name="Device-name" type="xs:string"/>
            <xs:element name="Device-description" type="xs:string"/>
            <xs:element name="Device-purpose" type="xs:string"/>
            <xs:element name="Device-classification" type="rdm:radiobutton"/>
            <xs:element name="Device-serial-no" type="xs:string"/>
            <xs:element name="sterile" type="rdm:yes-no"/>
            <xs:element name="measuring_function" type="rdm:yes-no"/>
            <xs:element name="reusable" type="rdm:yes-no"/>
            <!-- 2.2.4.2 -->
            <xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
            <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>
            <!-- 2.2.4.3 -->
            <xs:element name="confirm-compliance" type="rdm:yes-no"/>
            <xs:element name="explain-no" type="xs:string"/>
```

```xml
        <xs:element name="specify-yes" type="rdm:radiobutton"/>
        <!-- 2.2.4.4 -->
        <xs:element name="Contact-details">
          <xs:complexType>
            <xs:complexContent>
              <xs:extension base="rdm:contact-details-type">
                <xs:sequence>
                    <xs:element name="Telephone" type="xs:string"/>
                    <xs:element name="Email" type="xs:string"/>
                    <xs:element name="Number" type="xs:string"/>
                </xs:sequence>
              </xs:extension>
            </xs:complexContent>
          </xs:complexType>
        </xs:element>
      </xs:sequence>
    </xs:complexType>
</xs:element>

<xs:element name="Med-devices-checkbox-c" type="rdm:yes-no"/>
<xs:element name="Med-devices-subSections-c" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <!-- 2.2.4.1 -->
      <xs:element name="Device-name" type="xs:string"/>
      <xs:element name="Device-description" type="xs:string"/>
       <xs:element name="Device-purpose" type="xs:string"/>
      <xs:element name="Device-classification" type="rdm:radiobutton"/>
      <xs:element name="Device-serial-no" type="xs:string"/>
      <xs:element name="sterile" type="rdm:yes-no"/>
      <xs:element name="measuring_function" type="rdm:yes-no"/>
      <xs:element name="reusable" type="rdm:yes-no"/>
      <!-- 2.2.4.2 -->
      <xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
      <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>
      <!-- 2.2.4.3 -->
      <xs:element name="confirm-compliance" type="rdm:yes-no"/>
      <xs:element name="explain-no" type="xs:string"/>
      <xs:element name="specify-yes" type="rdm:radiobutton"/>
      <!-- 2.2.4.4 -->
      <xs:element name="Contact-details">
        <xs:complexType>
          <xs:complexContent>
            <xs:extension base="rdm:contact-details-type">
              <xs:sequence>
                  <xs:element name="Telephone" type="xs:string"/>
                  <xs:element name="Email" type="xs:string"/>
                  <xs:element name="Number" type="xs:string"/>
              </xs:sequence>
            </xs:extension>
          </xs:complexContent>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

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```xml
<xs:element name="Med-devices-checkbox-d" type="rdm:yes-no"/>
<xs:element name="Med-devices-subSections-d" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <!-- 2.2.4.1 -->
      <xs:element name="Device-name" type="xs:string"/>
      <xs:element name="Device-description" type="xs:string"/>
      <xs:element name="Device-purpose" type="xs:string"/>
      <xs:element name="Device-classification" type="rdm:radiobutton"/>
      <xs:element name="Device-serial-no" type="xs:string"/>
      <xs:element name="sterile" type="rdm:yes-no"/>
      <xs:element name="measuring_function" type="rdm:yes-no"/>
      <xs:element name="reusable" type="rdm:yes-no"/>
      <!-- 2.2.4.2 -->
      <xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
      <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>
      <!-- 2.2.4.3 -->
      <xs:element name="confirm-compliance" type="rdm:yes-no"/>
      <xs:element name="explain-no" type="xs:string"/>
      <xs:element name="specify-yes" type="rdm:radiobutton"/>
      <!-- 2.2.4.4 -->
      <xs:element name="Contact-details">
        <xs:complexType>
          <xs:complexContent>
            <xs:extension base="rdm:contact-details-type">
              <xs:sequence>
                <xs:element name="Telephone" type="xs:string"/>
                <xs:element name="Email" type="xs:string"/>
                <xs:element name="Number" type="xs:string"/>
              </xs:sequence>
            </xs:extension>
          </xs:complexContent>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>

<xs:element name="Med-devices-checkbox-e" type="rdm:yes-no"/>
<xs:element name="Med-devices-subSections-e" maxOccurs="unbounded">
  <xs:complexType>
    <xs:sequence>
      <!-- 2.2.4.1 -->
      <xs:element name="Device-name" type="xs:string"/>
      <xs:element name="Device-description" type="xs:string"/>
      <xs:element name="Device-purpose" type="xs:string"/>
      <xs:element name="Device-classification" type="rdm:radiobutton"/>
      <xs:element name="Device-serial-no" type="xs:string"/>
      <xs:element name="sterile" type="rdm:yes-no"/>
      <xs:element name="measuring_function" type="rdm:yes-no"/>
      <xs:element name="reusable" type="rdm:yes-no"/>
      <!-- 2.2.4.2 -->
      <xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
      <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>
```

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```xml
<!-- 2.2.4.3 -->
<xs:element name="confirm-compliance" type="rdm:yes-no"/>
<xs:element name="explain-no" type="xs:string"/>
<xs:element name="specify-yes" type="rdm:radiobutton"/>
<!-- 2.2.4.4 -->
<xs:element name="Contact-details">
  <xs:complexType>
    <xs:complexContent>
      <xs:extension base="rdm:contact-details-type">
        <xs:sequence>
          <xs:element name="Telephone" type="xs:string"/>
          <xs:element name="Email" type="xs:string"/>
          <xs:element name="Number" type="xs:string"/>
        </xs:sequence>
      </xs:extension>
    </xs:complexContent>
  </xs:complexType>
</xs:element>
                </xs:sequence>
              </xs:complexType>
            </xs:element>
          </xs:sequence>
        </xs:complexType>
      </xs:element>

<!-- 2.2.5 -->
<xs:element name="Companion-diagnostic">
  <xs:complexType>
    <xs:sequence>
      <xs:element name="companion-diagnosis-rb" type="rdm:yes-no"/>
      <xs:element name="sSections2_2_5_2-4" maxOccurs="unbounded">
        <xs:complexType>
          <xs:sequence>
            <xs:element name="Device-info" type="xs:string"/>
            <xs:element name="competent_Authority_planned" type="xs:string"/>
            <xs:element name="Notified-body">
              <xs:complexType>
                <xs:sequence>
                  <xs:element name="Contact-details">
                    <xs:complexType>
                      <xs:complexContent>
                        <xs:extension base="rdm:contact-details-type">
                          <xs:sequence>
                            <xs:element name="Telephone" type="xs:string"/>
                            <xs:element name="Email" type="xs:string"/>
                            <xs:element name="Number" type="xs:string"/>
                          </xs:sequence>
                        </xs:extension>
                      </xs:complexContent>
                    </xs:complexType>
                  </xs:element>
                </xs:sequence>
              </xs:complexType>
```

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```
            </xs:element>
          </xs:sequence>
        </xs:complexType>
      </xs:element>
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

b. For VARIATION

variations XSD changes:

(This is part of variations)

1)

<mark>Original:</mark>

```xml
<xs:element name="typeIAIN" type="rdm:yes-no"/>
<xs:element name="typeIA" type="rdm:yes-no"/>
<xs:element name="typeIBUnforeseen" type="rdm:yes-no"/>
<xs:element name="typeIBForeseen" type="rdm:yes-no"/>
<xs:element name="typeII" type="rdm:yes-no"/>
<xs:element name="typeIIArt29" type="rdm:yes-no"/>
<xs:element name="applicationType" type="rdm:radiobutton"/>
<xs:element name="includeLineExtension" type="rdm:yes-no"/>
<xs:element name="workshare" type="rdm:yes-no"/>
<xs:element name="igApplication" type="rdm:yes-no"/>
<xs:element name="indication" type="rdm:yes-no"/>
<xs:element name="paediatricIndication" type="rdm:yes-no"/>
<xs:element name="safety" type="rdm:yes-no"/>
<xs:element name="followingUrgentSafetyRestriction" type="rdm:yes-no"/>
<xs:element name="Quality" type="rdm:yes-no"/>
<xs:element name="AnnualVariation" type="rdm:yes-no"/>
<xs:element name="targetSpecies" type="rdm:yes-no"/>
<xs:element name="other" type="rdm:yes-no"/>
<xs:element name="covidSubstanceChange" type="rdm:yes-no"/>
<xs:element name="medicalDevice" type="rdm:yes-no"/>
<xs:element name="maHolder" maxOccurs="unbounded">
```

<mark>Changed to:</mark>

```xml
<xs:element name="typeIAIN" type="rdm:yes-no"/>
<xs:element name="typeIA" type="rdm:yes-no"/>
<xs:element name="typeIBUnforeseen" type="rdm:yes-no"/>
<xs:element name="typeIBForeseen" type="rdm:yes-no"/>
<xs:element name="typeII" type="rdm:yes-no"/>
<xs:element name="typeIIArt29" type="rdm:yes-no"/>
<xs:element name="applicationType" type="rdm:radiobutton"/>
<xs:element name="includeLineExtension" type="rdm:yes-no"/>
<xs:element name="workshare" type="rdm:yes-no"/>
<xs:element name="indication" type="rdm:yes-no"/>
<xs:element name="paediatricIndication" type="rdm:yes-no"/>
<xs:element name="safety" type="rdm:yes-no"/>
<xs:element name="followingUrgentSafetyRestriction" type="rdm:yes-no"/>
<xs:element name="Quality" type="rdm:yes-no"/>
<xs:element name="AnnualVariation" type="rdm:yes-no"/>
<xs:element name="targetSpecies" type="rdm:yes-no"/>
<xs:element name="other" type="rdm:yes-no"/>
```

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```
<xs:element name="covidSubstanceChange" type="rdm:yes-no"/>
<xs:element name="medicalDevice" type="rdm:yes-no"/>
<xs:element name="maHolder" maxOccurs="unbounded">
```

2)

Added new section

```xml
<!-- 4d section -->
              <xs:element name="VariationPurpose" minOccurs="0">
                <xs:complexType>
                  <xs:sequence>
                    <!-- <xs:element name="not-applicable" type="rdm:yes-no"/>  -->

                    <xs:element name="change-to-device">
                      <xs:complexType>
                        <xs:sequence>
                          <xs:element name="change-to-device-cb" type="rdm:yes-no"/>
                            <!-- type of device affected by this variation - checkboxes a,b,c,d,e -->
                          <xs:element name="Med-devices-checkboxes" maxOccurs="unbounded" minOccurs="0">
                            <xs:complexType>
                              <xs:sequence>
                              <xs:element name="Med-devices-checkbox-a" type="rdm:yes-no"/>
                              <xs:element name="Med-devices-subSections-a" maxOccurs="unbounded">
                              <xs:complexType>
                              <xs:sequence>
                              <!-- 2.2.4.1 -->
                              <xs:element name="Device-name" type="xs:string"/>
                              <xs:element name="Device-description" type="xs:string"/>
                              <xs:element name="Device-purpose" type="xs:string"/>
                              <xs:element name="Device-classification" type="rdm:radiobutton"/>
                              <xs:element name="Device-serial-no" type="xs:string"/>
                              <xs:element name="sterile" type="rdm:yes-no"/>
                              <xs:element name="measuring_function" type="rdm:yes-no"/>
                              <xs:element name="reusable" type="rdm:yes-no"/>

                              <!-- 2.2.4.2 -->
                              <xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
                              <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>

                              <!-- 2.2.4.3 -->
                              <xs:element name="confirm-compliance" type="rdm:yes-no"/>
                              <xs:element name="explain-no" type="xs:string"/>
                              <xs:element name="specify-yes" type="rdm:radiobutton"/>

                              <!-- 2.2.4.4 -->
                              <xs:element name="Contact-details">
                                  <xs:complexType>
                                    <xs:complexContent>
                                      <xs:extension base="rdm:contact-details-type">
                                        <xs:sequence>
                                          <xs:element name="Telephone" type="xs:string"/>
                                          <xs:element name="Email" type="xs:string"/>
                                          <xs:element name="Number" type="xs:string"/>
                                        </xs:sequence>
                                      </xs:extension>
```

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```xml
                    </xs:complexContent>
                </xs:complexType>
            </xs:element>
        </xs:sequence>
        </xs:complexType>
    </xs:element>
        <xs:element name="Med-devices-checkbox-b" type="rdm:yes-no"/>
        <xs:element name="Med-devices-subSections-b" maxOccurs="unbounded">
            <xs:complexType>
                <xs:sequence>
        <!-- 2.2.4.1 -->
        <xs:element name="Device-name" type="xs:string"/>
        <xs:element name="Device-description" type="xs:string"/>
        <xs:element name="Device-purpose" type="xs:string"/>
        <xs:element name="Device-classification" type="rdm:radiobutton"/>
        <xs:element name="Device-serial-no" type="xs:string"/>
        <xs:element name="sterile" type="rdm:yes-no"/>
        <xs:element name="measuring_function" type="rdm:yes-no"/>
        <xs:element name="reusable" type="rdm:yes-no"/>


        <!-- 2.2.4.2 -->
        <xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
        <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>


        <!-- 2.2.4.3 -->
        <xs:element name="confirm-compliance" type="rdm:yes-no"/>
        <xs:element name="explain-no" type="xs:string"/>
        <xs:element name="specify-yes" type="rdm:radiobutton"/>


        <!-- 2.2.4.4 -->
        <xs:element name="Contact-details">
            <xs:complexType>
                <xs:complexContent>
                    <xs:extension base="rdm:contact-details-type">
                        <xs:sequence>
                            <xs:element name="Telephone" type="xs:string"/>
                            <xs:element name="Email" type="xs:string"/>
                            <xs:element name="Number" type="xs:string"/>
                        </xs:sequence>
                    </xs:extension>
                </xs:complexContent>
            </xs:complexType>
        </xs:element>
            </xs:sequence>
        </xs:complexType>
    </xs:element>


        <xs:element name="Med-devices-checkbox-c" type="rdm:yes-no"/>
        <xs:element name="Med-devices-subSections-c" maxOccurs="unbounded">
        <xs:complexType>
        <xs:sequence>
        <!-- 2.2.4.1 -->
        <xs:element name="Device-name" type="xs:string"/>
        <xs:element name="Device-description" type="xs:string"/>
        <xs:element name="Device-purpose" type="xs:string"/>
```

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```xml
    <xs:element name="Device-classification" type="rdm:radiobutton"/>
    <xs:element name="Device-serial-no" type="xs:string"/>
    <xs:element name="sterile" type="rdm:yes-no"/>
    <xs:element name="measuring_function" type="rdm:yes-no"/>
    <xs:element name="reusable" type="rdm:yes-no"/>


    <!-- 2.2.4.2 -->
    <xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
    <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>


    <!-- 2.2.4.3 -->
    <xs:element name="confirm-compliance" type="rdm:yes-no"/>
    <xs:element name="explain-no" type="xs:string"/>
    <xs:element name="specify-yes" type="rdm:radiobutton"/>


    <!-- 2.2.4.4 -->
    <xs:element name="Contact-details">
        <xs:complexType>
          <xs:complexContent>
            <xs:extension base="rdm:contact-details-type">
              <xs:sequence>
                <xs:element name="Telephone" type="xs:string"/>
                <xs:element name="Email" type="xs:string"/>
                <xs:element name="Number" type="xs:string"/>
              </xs:sequence>
            </xs:extension>
          </xs:complexContent>
        </xs:complexType>
    </xs:element>
    </xs:sequence>
    </xs:complexType>
</xs:element>

    <xs:element name="Med-devices-checkbox-d" type="rdm:yes-no"/>
    <xs:element name="Med-devices-subSections-d" maxOccurs="unbounded">
    <xs:complexType>
    <xs:sequence>
    <!-- 2.2.4.1 -->
    <xs:element name="Device-name" type="xs:string"/>
    <xs:element name="Device-description" type="xs:string"/>
    <xs:element name="Device-purpose" type="xs:string"/>
    <xs:element name="Device-classification" type="rdm:radiobutton"/>
    <xs:element name="Device-serial-no" type="xs:string"/>
    <xs:element name="sterile" type="rdm:yes-no"/>
    <xs:element name="measuring_function" type="rdm:yes-no"/>
    <xs:element name="reusable" type="rdm:yes-no"/>


    <!-- 2.2.4.2 -->
    <xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
    <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>


    <!-- 2.2.4.3 -->
    <xs:element name="confirm-compliance" type="rdm:yes-no"/>
    <xs:element name="explain-no" type="xs:string"/>
    <xs:element name="specify-yes" type="rdm:radiobutton"/>
```

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```xml
<!-- 2.2.4.4 -->
<xs:element name="Contact-details">
    <xs:complexType>
        <xs:complexContent>
            <xs:extension base="rdm:contact-details-type">
                <xs:sequence>
                    <xs:element name="Telephone" type="xs:string"/>
                    <xs:element name="Email" type="xs:string"/>
                    <xs:element name="Number" type="xs:string"/>
                </xs:sequence>
            </xs:extension>
        </xs:complexContent>
    </xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>
</xs:element>

<xs:element name="Med-devices-checkbox-e" type="rdm:yes-no"/>
<xs:element name="Med-devices-subSections-e" maxOccurs="unbounded">
<xs:complexType>
<xs:sequence>
<!-- 2.2.4.1 -->
<xs:element name="Device-name" type="xs:string"/>
<xs:element name="Device-description" type="xs:string"/>
<xs:element name="Device-purpose" type="xs:string"/>
<xs:element name="Device-classification" type="rdm:radiobutton"/>
<xs:element name="Device-serial-no" type="xs:string"/>
<xs:element name="sterile" type="rdm:yes-no"/>
<xs:element name="measuring_function" type="rdm:yes-no"/>
<xs:element name="reusable" type="rdm:yes-no"/>

<!-- 2.2.4.2 -->
<!-- check if Manufacture-contact-details is repeatable -->
<xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
<xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>

<!-- 2.2.4.3 -->
<xs:element name="confirm-compliance" type="rdm:yes-no"/>
<xs:element name="explain-no" type="xs:string"/>
<xs:element name="specify-yes" type="rdm:radiobutton"/>

<!-- 2.2.4.4 -->
<xs:element name="Contact-details">
    <xs:complexType>
        <xs:complexContent>
            <xs:extension base="rdm:contact-details-type">
                <xs:sequence>
                    <xs:element name="Telephone" type="xs:string"/>
                    <xs:element name="Email" type="xs:string"/>
                    <xs:element name="Number" type="xs:string"/>
                </xs:sequence>
            </xs:extension>
        </xs:complexContent>
</xs:complexType>
```

```xml
                    </xs:complexType>
                </xs:element>
            </xs:sequence>
            </xs:complexType>
        </xs:element>
        </xs:sequence>
    </xs:complexType>
</xs:element>

<xs:element name="new-device">
    <xs:complexType>
        <xs:sequence>
            <xs:element name="new-device-cb" type="rdm:yes-no"/>
            <!-- type of device affected by this variation - checkboxes a,b,c,d,e -->
            <xs:element name="Med-devices-checkboxes" maxOccurs="unbounded" minOccurs="0">
                <xs:complexType>
                    <xs:sequence>
                        <xs:element name="Med-devices-checkbox-a" type="rdm:yes-no"/>
                        <xs:element name="Med-devices-subSections-a" maxOccurs="unbounded">
                        <xs:complexType>
                        <xs:sequence>
                        <!-- 2.2.4.1 -->
                        <xs:element name="Device-name" type="xs:string"/>
                        <xs:element name="Device-description" type="xs:string"/>
                        <xs:element name="Device-purpose" type="xs:string"/>
                        <xs:element name="Device-classification" type="rdm:radiobutton"/>
                        <xs:element name="Device-serial-no" type="xs:string"/>
                        <xs:element name="sterile" type="rdm:yes-no"/>
                        <xs:element name="measuring_function" type="rdm:yes-no"/>
                        <xs:element name="reusable" type="rdm:yes-no"/>

                        <!-- 2.2.4.2 -->
                        <xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
                        <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>

                        <!-- 2.2.4.3 -->
                        <xs:element name="confirm-compliance" type="rdm:yes-no"/>
                        <xs:element name="explain-no" type="xs:string"/>
                        <xs:element name="specify-yes" type="rdm:radiobutton"/>

                        <!-- 2.2.4.4 -->
                        <xs:element name="Contact-details">
                            <xs:complexType>
                                <xs:complexContent>
                                    <xs:extension base="rdm:contact-details-type">
                                        <xs:sequence>
                                            <xs:element name="Telephone" type="xs:string"/>
                                            <xs:element name="Email" type="xs:string"/>
                                            <xs:element name="Number" type="xs:string"/>
                                        </xs:sequence>
                                    </xs:extension>
                                </xs:complexContent>
```

eAF DES Change Summary

```xml
                    </xs:complexType>
                </xs:element>
            </xs:sequence>
        </xs:complexType>
    </xs:element>
        <xs:element name="Med-devices-checkbox-b" type="rdm:yes-no"/>
        <xs:element name="Med-devices-subSections-b" maxOccurs="unbounded">
        <xs:complexType>
        <xs:sequence>
        <!-- 2.2.4.1 -->
        <xs:element name="Device-name" type="xs:string"/>
        <xs:element name="Device-description" type="xs:string"/>
        <xs:element name="Device-purpose" type="xs:string"/>
        <xs:element name="Device-classification" type="rdm:radiobutton"/>
        <xs:element name="Device-serial-no" type="xs:string"/>
        <xs:element name="sterile" type="rdm:yes-no"/>
        <xs:element name="measuring_function" type="rdm:yes-no"/>
        <xs:element name="reusable" type="rdm:yes-no"/>


        <!-- 2.2.4.2 -->
        <xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
        <xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>


        <!-- 2.2.4.3 -->
        <xs:element name="confirm-compliance" type="rdm:yes-no"/>
        <xs:element name="explain-no" type="xs:string"/>
        <xs:element name="specify-yes" type="rdm:radiobutton"/>


        <!-- 2.2.4.4 -->
        <xs:element name="Contact-details">
            <xs:complexType>
              <xs:complexContent>
                <xs:extension base="rdm:contact-details-type">
                  <xs:sequence>
                    <xs:element name="Telephone" type="xs:string"/>
                    <xs:element name="Email" type="xs:string"/>
                    <xs:element name="Number" type="xs:string"/>
                  </xs:sequence>
                </xs:extension>
              </xs:complexContent>
            </xs:complexType>
        </xs:element>
            </xs:sequence>
          </xs:complexType>
        </xs:element>


        <xs:element name="Med-devices-checkbox-c" type="rdm:yes-no"/>
        <xs:element name="Med-devices-subSections-c" maxOccurs="unbounded">
        <xs:complexType>
        <xs:sequence>
        <!-- 2.2.4.1 -->
        <xs:element name="Device-name" type="xs:string"/>
        <xs:element name="Device-description" type="xs:string"/>
        <xs:element name="Device-purpose" type="xs:string"/>
        <xs:element name="Device-classification" type="rdm:radiobutton"/>
```

eAF DES Change Summary

```xml
<xs:element name="Device-serial-no" type="xs:string"/>
<xs:element name="sterile" type="rdm:yes-no"/>
<xs:element name="measuring_function" type="rdm:yes-no"/>
<xs:element name="reusable" type="rdm:yes-no"/>


<!-- 2.2.4.2 -->
<xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
<xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>


<!-- 2.2.4.3 -->
<xs:element name="confirm-compliance" type="rdm:yes-no"/>
<xs:element name="explain-no" type="xs:string"/>
<xs:element name="specify-yes" type="rdm:radiobutton"/>


<!-- 2.2.4.4 -->
<xs:element name="Contact-details">
    <xs:complexType>
      <xs:complexContent>
        <xs:extension base="rdm:contact-details-type">
          <xs:sequence>
            <xs:element name="Telephone" type="xs:string"/>
            <xs:element name="Email" type="xs:string"/>
            <xs:element name="Number" type="xs:string"/>
          </xs:sequence>
        </xs:extension>
      </xs:complexContent>
    </xs:complexType>
  </xs:element>
  </xs:sequence>
  </xs:complexType>
</xs:element>

<xs:element name="Med-devices-checkbox-d" type="rdm:yes-no"/>
<xs:element name="Med-devices-subSections-d" maxOccurs="unbounded">
<xs:complexType>
<xs:sequence>
<!-- 2.2.4.1 -->
<xs:element name="Device-name" type="xs:string"/>
<xs:element name="Device-description" type="xs:string"/>
<xs:element name="Device-purpose" type="xs:string"/>
<xs:element name="Device-classification" type="rdm:radiobutton"/>
<xs:element name="Device-serial-no" type="xs:string"/>
<xs:element name="sterile" type="rdm:yes-no"/>
<xs:element name="measuring_function" type="rdm:yes-no"/>
<xs:element name="reusable" type="rdm:yes-no"/>


<!-- 2.2.4.2 -->
<xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
<xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>


<!-- 2.2.4.3 -->
<xs:element name="confirm-compliance" type="rdm:yes-no"/>
<xs:element name="explain-no" type="xs:string"/>
<xs:element name="specify-yes" type="rdm:radiobutton"/>
```

eAF DES Change Summary

```xml
<!-- 2.2.4.4 -->
<xs:element name="Contact-details">
    <xs:complexType>
      <xs:complexContent>
        <xs:extension base="rdm:contact-details-type">
          <xs:sequence>
            <xs:element name="Telephone" type="xs:string"/>
            <xs:element name="Email" type="xs:string"/>
            <xs:element name="Number" type="xs:string"/>
          </xs:sequence>
        </xs:extension>
      </xs:complexContent>
    </xs:complexType>
  </xs:element>
  </xs:sequence>
  </xs:complexType>
</xs:element>

<xs:element name="Med-devices-checkbox-e" type="rdm:yes-no"/>
<xs:element name="Med-devices-subSections-e" maxOccurs="unbounded">
<xs:complexType>
<xs:sequence>
<!-- 2.2.4.1 -->
<xs:element name="Device-name" type="xs:string"/>
<xs:element name="Device-description" type="xs:string"/>
<xs:element name="Device-purpose" type="xs:string"/>
<xs:element name="Device-classification" type="rdm:radiobutton"/>
<xs:element name="Device-serial-no" type="xs:string"/>
<xs:element name="sterile" type="rdm:yes-no"/>
<xs:element name="measuring_function" type="rdm:yes-no"/>
<xs:element name="reusable" type="rdm:yes-no"/>

<!-- 2.2.4.2 -->
<xs:element name="Device-manufacturer" type="rdm:radiobutton"/>
<xs:element name="Manufacture-contact-details" type="rdm:contact-details-type"/>

<!-- 2.2.4.3 -->
<xs:element name="confirm-compliance" type="rdm:yes-no"/>
<xs:element name="explain-no" type="xs:string"/>
<xs:element name="specify-yes" type="rdm:radiobutton"/>

<!-- 2.2.4.4 -->
<xs:element name="Contact-details">
    <xs:complexType>
      <xs:complexContent>
        <xs:extension base="rdm:contact-details-type">
          <xs:sequence>
            <xs:element name="Telephone" type="xs:string"/>
            <xs:element name="Email" type="xs:string"/>
            <xs:element name="Number" type="xs:string"/>
          </xs:sequence>
        </xs:extension>
      </xs:complexContent>
    </xs:complexType>
  </xs:element>
```

```xml
                    </xs:sequence>
                  </xs:complexType>
                </xs:element>


              </xs:sequence>
            </xs:complexType>
          </xs:element>
        </xs:sequence>
      </xs:complexType>
    </xs:element>

    <!-- companion diagnostic  -->
    <xs:element name="Companion-diagnostic">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="companion-diagnosis-rb" type="rdm:yes-no"/>
          <xs:element name="sSections2_2_5_2-4" maxOccurs="unbounded">
            <xs:complexType>
            <xs:sequence>
              <xs:element name="Device-info" type="xs:string"/>
              <xs:element name="competent_Authority_planned" type="xs:string"/>
              <xs:element name="Notified-body">
                <xs:complexType>
                  <xs:sequence>
                    <xs:element name="Contact-details">
                      <xs:complexType>
                        <xs:complexContent>
                          <xs:extension base="rdm:contact-details-type">
                            <xs:sequence>
                            <xs:element name="Telephone" type="xs:string"/>
                            <xs:element name="Email" type="xs:string"/>
                            <xs:element name="Number" type="xs:string"/>
                            </xs:sequence>
                          </xs:extension>
                        </xs:complexContent>
                      </xs:complexType>
                    </xs:element>
                  </xs:sequence>
                </xs:complexType>
              </xs:element>
            </xs:sequence>
            </xs:complexType>
          </xs:element>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
```

3)
Original:

```xml
<xs:element name="Signatory" type="rdm:signatory"/>
```

Changed to:

eAF DES Change Summary

```xml
<xs:element name="Signatory">
  <xs:complexType>
    <xs:complexContent>
      <xs:extension base="rdm:signatory">
        <xs:sequence>
          <!-- new section under proof of payment -->
          <xs:element name="concern-other-Member-State" type="rdm:yes-no"/>
          <xs:element name="specify-yes" maxOccurs="unbounded">
            <xs:complexType>
              <xs:sequence>
                <xs:element name="country" type="rdm:control-term"/>
                <xs:element name="invented-name" type="xs:string"/>
                <xs:element name="submission-date" type="xs:date" minOccurs="0"/>
                <xs:element name="procedure-number" type="xs:string"/>
                <xs:element name="rbVariationStatus" type="rdm:radiobutton"/>
                <xs:element name="granting-date" type="xs:date" minOccurs="0"/>
                <xs:element name="refusal-date" type="xs:date" minOccurs="0"/>
                <xs:element name="withdrawal-date" type="xs:date" minOccurs="0"/>
              </xs:sequence>
            </xs:complexType>
          </xs:element>
          <!-- new section -->
          <!-- question1 -->
          <xs:element name="harmonisation-question1">
            <xs:complexType>
              <xs:sequence>
                <xs:element name="harmonised-ma" type="rdm:yes-no"/>
                <xs:element name="specify-yes" maxOccurs="unbounded">
                  <xs:complexType>
                    <xs:sequence>
                      <xs:element name="procedure-number" type="xs:string"/>
                      <xs:element name="specify-section" type="xs:string"/>
                    </xs:sequence>
                  </xs:complexType>
                </xs:element>
              </xs:sequence>
            </xs:complexType>
          </xs:element>


          <!-- question2 -->
          <xs:element name="harmonisation-question2">
            <xs:complexType>
              <xs:sequence>
                <xs:element name="harmonisation-achieved-worksharing" type="rdm:yes-no"/>
                <xs:element name="specify-yes" maxOccurs="unbounded">
                  <xs:complexType>
                    <xs:sequence>
                      <xs:element name="procedure-number" type="xs:string"/>
                      <xs:element name="specify-section" type="xs:string"/>
                    </xs:sequence>
                  </xs:complexType>
                </xs:element>
              </xs:sequence>
            </xs:complexType>
          </xs:element>
        </xs:sequence>
```

eAF DES Change Summary

```
        </xs:extension>
      </xs:complexContent>
    </xs:complexType>
  </xs:element>
```

eAF DES Change Summary

eAF dictionary XSD changes:

For SD-121617
(This is part of eAF_dictionary)

Original:

```
<xs:element name="ph-eur-cert">
  <xs:complexType>
        <xs:sequence>
                    <xs:element name="substance-certificate" type="rdm:substance-certificate"/>
        </xs:sequence>
  </xs:complexType>
</xs:element>
```

Changed to:

```
<xs:element name="ph-eur-cert">
  <xs:complexType>
        <xs:sequence>
                    <xs:element name="substance-certificate" type="rdm:substance-certificate" maxOccurs="unbounded"/>
        </xs:sequence>
  </xs:complexType>
</xs:element>
```

For SD-179089
(This is part of eAF_dictionary)

Original:

```
<xs:complexType name="shelf-life">
  <xs:sequence>
        <xs:element name="shelf-life-after-open" type="rdm:string30"/>
        <xs:element name="shelf-life-after-open-units" type="xs:string"/>
        <xs:element name="shelf-life-after-dilution" type="xs:string"/>
        <xs:element name="shelf-life-after-dilution-units" type="xs:string"/>
        <xs:element name="shelf-life-before-open" type="rdm:string30"/>
        <xs:element name="shelf-life-before-open-units" type="xs:string"/>
        <xs:element name="spfs" maxOccurs="unbounded">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="special-precaution-for-storage" type="rdm:control-term"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="spfsao" maxOccurs="unbounded">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="special-precaution-for-storage-after-open" type="rdm:control-term"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="spfsadr" maxOccurs="unbounded">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="special-precaution-for-storage-after-dilution-reconstitution" type="rdm:control-term"/>
                </xs:sequence>
            </xs:complexType>
```

```
        </xs:element>
        <xs:element name="shelf-life-duration" type="xs:string" minOccurs="0"/>
      </xs:sequence>
</xs:complexType>
```

Changed to:

```
<xs:complexType name="shelf-life">
  <xs:sequence>
        <xs:element name="shelf-life-after-open" type="rdm:string30"/>
        <xs:element name="shelf-life-after-open-units" type="xs:string"/>
        <xs:element name="shelf-life-after-dilution" type="xs:string"/>
        <xs:element name="shelf-life-after-dilution-units" type="xs:string"/>
        <xs:element name="shelf-life-before-open" type="rdm:string30"/>
        <xs:element name="shelf-life-before-open-units" type="xs:string"/>
        <xs:element name="spfs" maxOccurs="unbounded">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="special-precaution-for-storage" type="rdm:control-term"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="spfsao" maxOccurs="unbounded">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="special-precaution-for-storage-after-open" type="rdm:control-term"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="spfsadr" maxOccurs="unbounded">
            <xs:complexType>
                <xs:sequence>
                    <xs:element name="special-precaution-for-storage-after-dilution-reconstitution" type="rdm:control-term"/>
                </xs:sequence>
            </xs:complexType>
        </xs:element>
        <xs:element name="shelf-life-duration" type="xs:string" minOccurs="0"/>
      </xs:sequence>
</xs:complexType>
```