## WHO concept note and collaboration proposal for International Nomenclature, coding and classification of medical devices (ICMD)

### Name of person(s) submitting comments
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### Date of submission:
Sep. 6th, 2018

### Interest in ICMD:

### General comment on the concept note, especially on the principles:
On the regulatory point of view, it is beneficial to develop a global harmonized medical device nomenclature system which will is essential for international post-market information (recall, adverse events reporting) exchange. Since many countries (FDA, Japan, Australia) have developed or adopted nomenclature systems for regulatory purposes, the new ICMD system should be able to link to the current nomenclature systems (for example FDA product code, GMDN).

### Template for comments

<table>
<thead>
<tr>
<th>Line no.</th>
<th>Comment / Rationale</th>
<th>Proposed change / suggested text</th>
<th>Classification</th>
<th>Originator of the comments (for WHO use)</th>
</tr>
</thead>
</table>
| 1        | The ICMD system should be able to link to the current regulatory nomenclature systems. | New item  
c. Access of information  
vii. Can be linked to the current nomenclature systems (FDA Product Code, GMDN, UMDNS). | L=low  
M=medium  
H=high | |
| 2        |                      |                                  |                |                                          |
| 3        |                      |                                  |                |                                          |

Please add rows as necessary

If you would like to propose your nomenclature /coding or classification system from your institution/country, in order to support the development of an international system for medical devices, ICMD, please provide your information below:

**Name of the system:** TFDA Medical device classification system

**Website**
http://mdlicense.itri.org.tw/DB/MDClassification.aspx

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1/2
Please feel free to explain your proposal Reasons why your system can be used to support the development of an international system that could be used by all medical devices stakeholders. *(You would be contacted in September, once the responses are analysed)*

The TFDA medical device classification system is developed for the regulatory purpose. This system is similar to US FDA regulation numbers and it is reviewed and updated annually. Since this system is based on Traditional Chinese (Mandarin) and has English translations, it will be helpful for ICMD in language aspects.

<table>
<thead>
<tr>
<th>Owner</th>
<th>TFDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>ROC</td>
</tr>
<tr>
<td>Language</td>
<td>Traditional Chinese (Mandarin), English</td>
</tr>
</tbody>
</table>

*Kindly send this form to* medicaldevices@who.int *before 7 September - thank you.*