DITTA contribution on Unique Device Identification (UDI)

at the occasion of the IMDRF meetings in San Francisco, 25-27 March 2014

DITTA congratulates the IMDRF for developing a common view to improve traceability of medical devices globally and, more specifically, on Unique Device Identification (UDI).

DITTA is a strong supporter of global harmonization of regulatory frameworks for medical devices. We appreciate the opportunity to have been directly involved in this IMDRF Work Item since its launch and would like to use the opportunity of this Forum to articulate our key wish list:

1. **Align with existing regulations on UDI (e.g., the US FDA Final Rule)**
2. **Maintain label placement/product packaging without changes**
3. **Align with regard to Software as a Medical Device (SaMD)**
4. **Agree on clear and unambiguous specification of the UDI data elements**

1. Align with existing regulations on UDI (e.g., the US FDA UDI final rule)

We acknowledge and appreciate the efforts by IMDRF regulators to define UDI regulations for their respective jurisdiction. DITTA is also pleased with the issuance of the US FDA final rule. We believe the FDA framework serves as an example that deserves to be closely monitored and that may be replicated by others. To achieve the overarching goal of a globally harmonized UDI framework, we urge the IMDRF Management Committee to continue its support of a framework that mirrors that which FDA has established. This would significantly reduce work for both regulatory agencies and manufacturers, increase harmonization and drive global UDI adoption. With a globally harmonized approach to UDI, traceability of medical devices increases worldwide. We urge the IMDRF Management Committee, with support of the IMDRF UDI Working Group, to align its work with the FDA Final Rule.

2. Maintain label placement/product packaging without changes

It is critical that the UDI remains in the existing location of the label/packaging with which the product was registered/approved/licensed. No additional labels or changes to product packaging should be required. A consistent application of UDI labeling helps to contain the burden of implementation.

3. Align with regard to Software as a Medical Device

DITTA finds the IMDRF's N7 guidance on UDI very restrictive in its definition of when changes to Software as a Medical Device (SaMD) require a new UDI-Device Identifier (DI) and/or a new UDI-Production Identifier (PI). This approach is disconnected from the approach US FDA has taken in its Final Rule. DITTA is concerned that such a detailed definition of when changes to a Software as a Medical Device (SaMD) would require a new UDI could be misinterpreted and potentially lead to unwarranted product registrations. A failure to act on this issue would result in a significant burden for regulators and manufacturers.

19 March 2014

DITTA supports the approach FDA has taken on UDI implementation for Standalone Software and urges the Management Committee to align the final IMDRF UDI guidance on this matter with the FDA final UDI rule.

4. Agree on clear and unambiguous specification of the UDI data elements

True global implementation of UDI depends on defining a set of core data elements common for **all** databases.

Therefore, DITTA recommends:

- The core data elements of the UDI should be identical in every jurisdiction, and may be provided in English or in the official language(s) and codes used in the respective jurisdiction
- If a jurisdiction requires additional information – similar to additional labeling components required on the label or/and the Instructions for Use – there should be a process devised for dealing with this.

The concept of a 'global UDI' will be merely theoretical if UDIs are expected to transport different sets of data in different jurisdictions. As stated earlier, an unambiguous core data set that is identical across all databases is crucial, and it can directly serve as a requirement specification for implementing the related IT infrastructure. DITTA urges all IMDRF members to continue working towards this important common goal.

DITTA stands steadfast in our commitment to work with IMDRF to ensure One World, One UDI.

DITTA is a global association of manufacturers that represent medical imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers. Member companies manufacture: medical x-ray equipment; computed tomography (CT) scanners; ultrasound; nuclear imaging; radiation therapy equipment; magnetic resonance imaging (MRI); imaging information systems; medical software and health IT; and radiopharmaceuticals.

DITTA's membership currently includes ABIMED (Brazil), CAMDI (China), COCIR (Europe), IMEDA (Russia), ITAC (Canada), JIRA (Japan), KMDICA (Korea), MEDEC (Canada), MITA (United States) and THAIMED (Thailand).