

October 12, 2018

International Medical Device Regulators Forum (IMDRF)

Attn: Salvatore Scalzo, UDI Working Group Chair

salvatore.scalzo@ec.europa.eu

Re: **Initial Comments** of AIM North America on:

**IMDRF Unique Device Identification System (UDI System) Documents**

N48 - Unique Device Identification system (UDI system) Application Guide

N53 - Use of UDI Data Elements across different IMDRF Jurisdictions

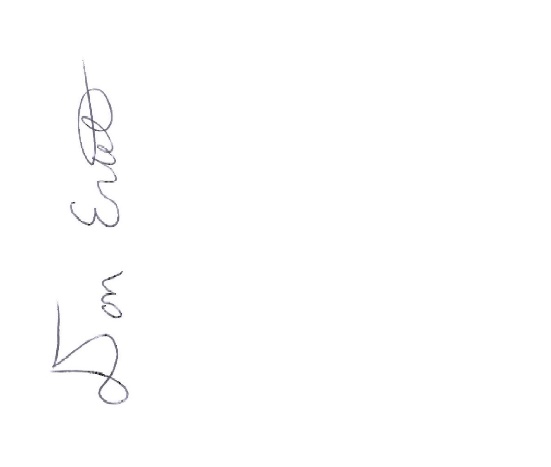
N54 - Recording Unique Device Identifiers in Electronic Health Sources

To Whom It May Concern:

We are pleased to submit the enclosed comments regarding the above referenced call for consultation which appeared on the [IMDRF website](http://www.imdrf.org/consultations/cons-udi-system-180712.asp).

These comments were prepared by members of the AIM North America Public Policy UDI Work Group, all of whom are subject matter experts of the design and application on automatic identification technology. AIM North America is an industry trade association that represents the providers and users of technologies, systems, and services that capture, manage, and integrate accurate data into larger information systems that improve processes enterprise-wide. AIM North America is a chapter of [AIM, Inc](http://www.aimglobal.org)., the trusted worldwide industry association for the automatic identification industry providing unbiased information, educational resources and standards to providers and users of these technologies for nearly 50 year.

AIM North America strongly supports and commends the IMDRF for its on-going program to implement automatic identification technologies for the identification and tracking of healthcare products.

As subject matter experts in both linear bar codes and 2-dimensional symbologies, AIM North America will be happy to respond to any technical support requests from the IMDRF about UDI implementation.

Sincerely Yours,

Don Ertel

AIM North America Board Chairman

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**IMDRF Draft Guidance Comment Form**

***UDI WG (PD1)/N48 - Unique Device Identification system (UDI system) Application Guide***

| **Date** | **Document** | |  |
| --- | --- | --- | --- |
| 10/12/18 | IMDRF  UDI Guidance Document | **AIM North America** | |

| Commenting Organization | Line number | Clause/ Subclause | Paragraph Figure/ Table | Type of comment (General, Technical. Editorial) | COMMENTS  NOTE: Please identify the issue clearly as to why the comment should support a change to the guidance | PROPOSED CHANGE  NOTE: Please provide suggested change in order for comment to be understood for discussion | OBSERVATIONS OF IMDRF |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **AIM North America** | Page 11 | Section 4.0 | Bullet 2 |  | Technical | When a device must bear a UDI direct marking, the UDI may be provided through either or both of the following: (1) ***easily readable plain-text*** or (2) automatic identification and data capture (AIDC) technology, or any alternative technology that will provide the UDI of the device on demand. 3) When space is a limitation, machine readable UDI symbol is preferred. 4) It is recommended that sans serif fonts be used  Note: AIM NA, at the request of the FDA, had a meeting to discuss print quality, verification, and validation. During this meeting, AIM NA noted that image recognition is not widely used and not fully developed. Thus recommend the UDI be conveyed via scannable codes due to the robustness built into the standards. | Encourage both, but if have space constraints, use AIDC mark.  Following the human factors recommendations of *ANSI/AAMI* *HE75:2009(R2013)* for medical devices, fonts shall with a minimum point size of 5.5 (Note: 1 point = 1/72”). Sans serif fonts are recommended to be used. |  |
| **AIM North America** | Page 13 | Section 6.2 |  | Technical | Direct mark example should be changed to data matrix code mark | datamatrix |  |
| **AIM North America** | Page 14 | Section 6.4 |  | Technical | There are standards missing. | **6.4 Auto Identification Data Capture (AIDC) representation of UDI**  There are a wide variety of AIDC carriers available; however, to meet the imperatives of the IMDRF UDI Guidance, the UDI should comply with the requirements of the global accredited issuing agencies/entities and the accepted AIDC standards, i.e., ISO/IEC 15459-2; ISO/IEC 15459-4; ISO/IEC 646; ISO/IEC 15415; ISO/IEC 15416; ISO/IEC 16022 ISO/IEC TR 29158.  Each issuing agency/entity has their own general technical specifications that include information on the carrier type, size, placement and quality in addition to recommendations about the human-readable presentation of the encoded data (for further information on issuing agencies/entities see Section 10.3 of this document).  Some carriers are only approved for specific applications (e.g. retail). Therefore it is imperative to understand the appropriate application of each carrier and allow the manufacturer to choose the appropriate carrier based upon the application for use.  For purpose of illustration, the images shown in Appendix B depict some of the most widely used AIDC carriers used in healthcare (medical devices and pharmaceuticals) today.  RFID may also be an acceptable AIDC technology and the associated standards ISO/IEC 18000, RFID Air Interface Protocols, ISO/IEC 15961.2, RFID Data Protocol. ISO/IEC 15963. RFID Unique Tag ID. Examples of RFID are provided in Appendix C5. |  |
| **AIM North America** | Page 14 | Section 6.5 |  | Technical | The use of barcode readers capable of reading direct part marks should be taken into account based on the types of devices and sub straights that will be scanned at the point of use. | Any evaluation of scanner or reader technology should take into account the range of bar code formats, sizes, and substrates that will be scanned at the point of care. It is recommended that scanners be capable of reading two-dimensional bar codes printed both on conventional labels and marked directly on implants and other medical devices. |  |
| **AIM North America** | Page 26 | Section 12.1.3 |  | Technical | Too vague; needs to be edited back to the FDA guidelines November 2017.  Study analysed (GS1 UCD) all UDI documentation methods previously presented by AdvaMed to the FDA, “Current Landscape of UDI Implementation: AdvaMed Ad Hoc Spine/Trauma Trays and UDI Working Group” June 5, 2017. Study reveals that AIDC technology utilized in the “sterile field” was the most accurate documentation method with the fewest human errors and presented complete UDI (DI+PI) and fastest method of UDI conveyance. In addition, the AIDC “sterile field” methodology allowed for the UDI to be “identifiable prior to implantation” as statutorily required. | Too vague; needs to be edited back to the FDA guidelines November 2017.   * Note that the UDI requirement of 39121 CFR 801.45(a) does not always apply: Either when any type of direct marking would interfere with the safety or effectiveness of the device, or when direct marking it is not technologically feasible.   <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM452262.pdf> |  |
| **AIM North America** | Page 27 | 1st paragraph |  | Technical |  | Add reference to ISO as well |  |
| **AIM North America** | Page 27 | Images |  | Technical | Add implant direct mark images – | Add attached images |  |
| **AIM North America** | Page 27 | Below bullet “b” |  | Technical | Add after “The applicability…..questions.” | However, the FDA expects the labeler to document the rationale for the technological infeasibility in the DHF. Because it is expected that direct marking technology will advance over time, exceptions under 21 CFR 801.45(d)(1) and 21 CFR 801.45(d)(2) may lose their applicability over time and thus labelers should periodically reassess their use of those exceptions. |  |
| **AIM North America** | Page 49 | Annex F |  | Technical | Attached is a comprehensive study performed by "add’n solutions ", a EU laser marking service provider, on the resilience of nanosecond fiber laser marked UDIs on surgical instruments. The study validates and offers empirical data on the reliable resistance of the laser marks after 500 sterilization and cleaning cycles.    Add the statement to the right to page 49. | The European and American UDI Directives make no specific statements about the stability of laser markings. However, in general they require long-term stability to guarantee complete traceability. Consequently, manufacturers are challenged to ensure sustainable and stable laser marked contents. Laser markings are subject to fading or even corrosion if all steps in the process have not been well aligned to each other, or if the optimal laser and marking parameters have not been thoroughly defined.  With a precisely matched process, "add’n solutions" has marked surgical instruments with nanosecond fiber lasers, followed by a cleaning and passivation cycles. "add’n solutions" has then studied the stability and reliability of the laser marks on these instruments after they have been sterilized and cleaned 500 times with high alkaline cleaners (pH value of 14). The process and the results are described in the attached white paper. |  |
| **AIM North America** | Page 50 |  |  | Technical | The images used in the **Laser Marking** section do not show the mark in a favourable manner due to lighting issues. The same lighting should be used in both the ns-Laser and ps-Laser graphics. Updated images/copy are attached. |  |  |
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