

Document number: GHTF/AHWG Title: Unique Device Identification (UDI) System

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Comment Number	Affiliation (e.g. FDA)	Page / Section /	Editorial or Technical	Comment and rationale	Proposed revised text	SG1 Decision (& date)
1.		4/4	Editorial	The UDI system should be not only globally applicable , but also harmonized	...a single globally harmonized UDI system...	
2.		4/6	Technical	On regulatory compliance: A harmonised approach would improve traceability and adverse event tracking. But it is necessary to approach this based on risk classes as also suggested by Eucomed and Advamed.	See comments	
3.		6/4..... throughout	Editorial	The terms “static” & “dynamic” should be eliminated when referencing UDI Code. For clarity – the terms “Device Identifier” & “Production Identifier” are sufficient and self-explanatory. When “static” and “dynamic” are used independently – they are confusing and ill defined.	See comments	
4.		6/3 International Standards	Editorial	The “remark” is rather broad. Although there are ISO AIDC standards, they are not all used in the healthcare standards as developed.	Delete specific references to avoid that one or more are missing.	

5.		6/4	Editorial	Coding system should be globally standardized	...through a globally standardized coding system...	
6.		7-8/5	Technical	Implementation plan needs specificity if different levels of marking required. – is it Direct Part Mark (on the device), Unit of Use level (primary package), Inventory Shelf Box (secondary package), or the Case level (tertiary package). Practicality, feasibility and usage in a clinical environment should be an important element of consideration – cannot be based on risk alone. The impact of the different levels of marking varies tremendously.	Specify the level of marking required for different product groups. Primary (multipack only?), Secondary, etc. or refer to the international standards.	
7.		7/1	Technical	Expiration date only is enough, manufacturing date is not needed	Delete manufacture date	
8.		7/3	Technical	Country specific barcodes should be replaced by UDI	See comment	
9.		8/1	Editorial	Rephrase	GMDN should be used as globally accepted nomenclature in the UDID.	
10.		8/2	Technical	A timeframe of some years must be given to implement	See comment	
11.		8/5.7	Technical	Add further definition on timelines	...throughout the intended lifetime of the device or five years after the production of the last device for products without expiry date or five years after the last use of a product with expiry date – whatever is longer	
12.		8/6.1	Editorial	Further clarification on UDI	UDI code is the combination of static	

				code definition	information (device identifier) and dynamic information (production identifier) representing a product and its package configuration.	
13.		8/6.2	Technical	The rules for UDI allocation should follow the international healthcare standards' allocation rules, preferably GS1 GTIN allocation rules. The UDI represents the product and its package configuration.	See comments	
14.		8/5.3	Technical	Data carriers should be limited to those that are based on ISO, but also limited to those used by the existing global standards for healthcare.	Limit to the standards used in healthcare, preferably GS1 Healthcare	
15.		9/6.3	Technical	Clarification on alphanumeric	The UDI code static part (device identifier) is a "non-intelligent" numeric or alpha-numeric number that has no inherent meaning	
16.		9/6.4	Technical	Additional product identification should be according to regulatory requirements.	See comments	
17.		9/7.2	Technical	Reflect decisions of global standards bodies on carrier	The static and dynamic parts of the UDI Code may be expressed as concatenated or non-concatenated linear bar codes near to each other as allowed by existing global standards	
18.		9/7.4	Technical	If technology is not available throughout the entire supply chain (including patient bedside), if the data carrier on the label becomes unreadable, or if the technology breaks down, this creates a full stop	See comments	

				and there will be no way to identify the product by UDI. Must consider technology availability in all markets, specifically also in developing countries.		
19.		9/7.4	Technical	Direct part marking should be included	The human readable information and the AIDC format should both be placed on the label of the device or on the device itself.	
20.		9/7.5	Technical /Editorial	Clarify need for parallel usage of RFID and barcode as back-up	In case of RFID on labels, human readable information and a barcode should be provided in parallel.	
21.		9/7.6	Technical	Specific UDI allocation rules must first be developed for direct marking of devices to ensure referential integrity between the UDI on the device and the product package. Result could be completely different UDI on product than the product package. A GTIN represents a product and its package configuration.	See comments	
22.		9 and 10/7.6/7.7.7.8	Technical	Define packaging levels used in these paragraphs. Are the GS1 standards here accepted for the definition?	See comments	
23.		9/7.6	Technical	What is meant here by inference? Clarification is needed.	See comments	
24.		10/7.8	Editorial	Define "low risk" Does unit of use marking apply to	See comments	

				multipacks only or does it apply to the each as well?		
25.		9/7.7	Editorial	How is "package" defined? Primary, secondary, etc. need to be clearly defined.	See comments	
26.		9/7.6	Technical	Direct part marking of product must consider the practical usage in a clinical environment and the availability of the scan technology.	See comments	
27.		10/8.1	Technical	Another consideration should be the introduction of validation rules like only one GMDN code per product etc	See comments	
28.		11/8.3	Technical	It should be carefully considered which information must stay confidential	See comments	
29.		11/8.5		<p>Attributes needing clarity or definition:</p> <p>- Manufacturer Name The definition should clearly show whether manufacturer is the entity with legal responsibility for the product (placing the product on the market under his / her own name, or if this is intended to denote where the product was manufactured. Based on the GHTF document, I'm not sure what type of info is intended</p> <p>- Manufacturer Contact information: This kind of</p>	See comments	

			<p>information requires a structured format to enable machine-to-machine communication</p> <ul style="list-style-type: none"> - Nomenclature: Only one nomenclature should be used and that should be GMDN - Device Name (generic) not clear - is this not covered in GMDN? - Controlled by serial and/or lot/batch number and/or manufacturing and/or expiration date: For which purpose is this needed? Why a manufacturing date? Needs to be properly formatted also in Y/N option. - Quantity and Packaging: This information needs to be properly formatted – it is difficult and complex information. - Size including units of measure – this information is generally carried in the product Description making this redundant. Why is size tracked when other critical properties of the product are not? For example with a pacing lead, 30 cm would be tracked for a 30 cm lead, but no notation as to whether it is unipolar or bipolar, which is critical? Additionally, 	
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			<p>this information is captured more appropriately in the Product Description field.</p> <p>- Storage conditions: Clarification needed what the purpose is of this data. Need to be structured like in GDSN.</p> <p>- Sterility – this is not a device identification attribute and should be removed.</p> <p>- Labelled and /or IFU as containing allergens/materials of concern: There exists no global agree lists of material of concern. Clarification needed</p> <p>- Regional Authorized Representatives as labeled Further clarification is needed here - what exactly is requested. Structured approach needed. Could be relation of one GTIN to many representatives?</p> <p>URL for additional information: Issue of maintenance and to what exactly it should link? What is the intent? This is also not a device identification attribute.</p> <p>-Special Instructions for Use Not device identification</p>	
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				attribute – should be removed.		
30.		11/8.5		What about Product Description ?	Add	
31.		13		Better use a packaged product instead a direct marked product as this is the majority of products. Remove SN and make it generic.	See comment	