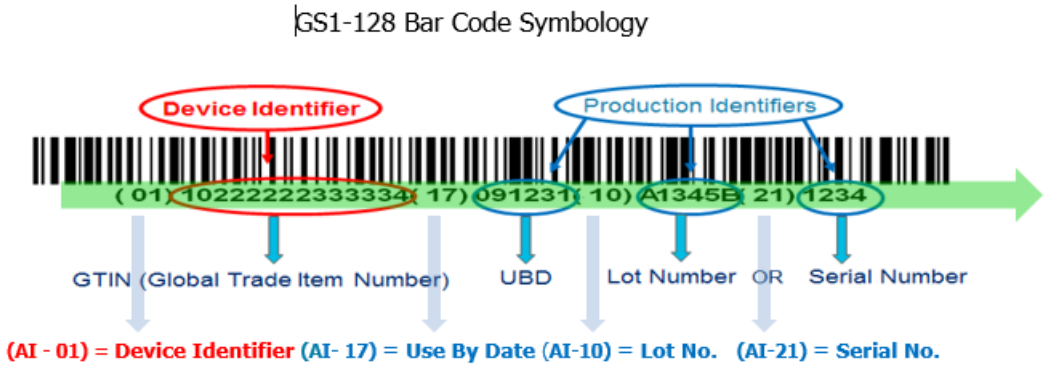
Invitation for hospitals to explore traceability solutions for non-sterile surgical sets

Solutions to capture full Unique Device Identifier (UDI-DI and UDI-PI)

This is an invitation following a request from the European Commission for healthcare institution stakeholders to participate in a joint working group with medical device manufacturers in the context of the UDI system introduced under the new Regulation (EU) 2017/745 ('MDR'). The goal of this working group is to find common viable solution(s) to ensure capture of data for traceability of individual devices within non-sterile surgical sets as required by the MDR.

Background

MDR Article 27(9)
Health institutions shall store and keep, – preferably by electronic means – the Unique Device Identifiers (UDIs) of the Class III implantable devices they have supplied, or with which they have been supplied.
MDR Annex VI:
The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. The UDI is comprised of the UDI-DI (device identifier – static part) and the UDI-PI (production identifier – dynamic part).



2D datamatrix: 
(01)10857674002017
(10) 1234AB

European Commission Factsheet for healthcare professionals and health institutions
https://ec.europa.eu/health/sites/default/files/md_newregulations/docs/healthcareprofessionals_factsheet_en.pdf

Purpose:

Engage healthcare stakeholders (Hospital Inventory, ERP, IT, and Supply Chain Management) and Manufacturers to find common viable solution(s) to capture UDI coded information for inclusion in hospital systems and traceability for individual devices within non-sterile surgical sets, per the new Regulation (EU) 2017/745 ('MDR') requirements. Due to the lack of certainty around workable traceability solution(s) that hospitals are able to implement, industry is seeking end-user collaboration in a working group:

1. to review the *attached* questionnaire responses to understand current hospital practices and needs for capturing UDI
2. to agree upon (an) existing MDR-compliant viable solution(s) to capture the full UDI (1 - 3 solutions)
3. to align practices of manufacturers providing full UDI to facilitate the capturing of full UDI by the healthcare institutions

In case you are interested to take part in the joint work, please contact: k.mate@medtecheurope.org **by 15 December 2021.**

In addition, hospital stakeholders are requested to fill out the following short survey https://www.surveymonkey.com/r/XZKP3M2 , which will serve as an important basis for the work.