VDDI
Dental Solutions.
German Manufacturers.

UDI

UDI arrived in Europe

SUMMARY

virtual UDIWORKSHOP
28th HealthCare Barcode Users Day 24.02.2021

Organizer: VDDI e.V

Cooperation partner for the event:

IFA CODINGSYSTEM

EDC EuroData Council

DENTAURUM

EUROPE IT Consulting GmbH
Softwareentwicklung und Beratung

REA VERIFIER

elmicron

28th HealthCare Barcode Users Day „UDI“

SUMMARY

of the virtual event on February 24th, 2021

John-Marco Fader (picture right), DENTAURUM and Chairman of the Joined Working Group AIDC welcomed the almost 100 virtual participants of the event and thanked for the great interest on behalf of the organizer VDDI e.V. The workshop character made it possible for the participants to ask questions via the "chat function", which the speaker answered in dialogue. This worked extremely well thanks to the discipline of the participants.

Dr. Harald Oehlmann, ELMICRON, started with the technical part “UDI MARKING, step by step”, and went into the characteristics of the UDI codes GS1, HIBC, IFA, as well as into the label structure with content, date format, emblems and the optional symbols with the associated “Human Readable Interpretation (HRI)”. The explanations also included the levels to be marked and the organization of the packaging levels. Explanations adressed how to check and and to document data quality in the code through the legally required “label inspection” and bridged to the following symbol quality session.
Wilfried Weigelt, REA Electronics, deepened the subject of "physical quality control" by providing information on the technical measurement of the barcode symbols, which is possible with the help of a "verifier" since the human eye does not recognize deviating details. The ISO standards for this, in which Wilfried Weigelt works directly, supply specific quality grades as measured values. The requirements for the minimum value, however, come from the specifications of the accredited "issuing agencies", for example at least grade "C" in the scale A (best) to D (failed). The paragraphs with the legal requirements for quality control from FDA and EU (MDR) were also mentioned. Examples of quality deviations and how these can arise were also shown.

Axel Röpke represented the “Information Center for Medicinal Specialties”, the IFA GmbH, as an EU-accredited "Issuing Agency" for UDI. IFA is traditionally the registry for the PZN’s, known for marking and identifying drugs. However, the IFA PZN database also contains a large proportion of medical devices. With the PZN update as PPN, this is now compliant with UDI-DI and UDI-PI, and using Data Matrix as data carrier. There is an exciting innovation here, because, as it was explained, IFA not only offers the 8-digit PZN format as UDI-DI, but also the "HPC Health Product Code" format. As with the HIBC, the manufacturer can thus create his own UDI-DI alphanumerically. This means that the IFA Coding System distinguishes itself as extremely flexible and universal for UDI-DI's in code and order reference.

UDI & EUDAMED and “How is the EU ticking” took up a large part of the second lecture by Dr. Harald Oehlmann. The "Single Registration Number -SRN", its delay until the "Date of Application" of the EUDAMED-UDI module (May 2022), the "BUDI" (BASIC UDI-DI) as MP group reference and the data elements for the UDI module of EUDAMED were explained in detail. The recommendation was given to carefully choose the product group under a BUDI, since the BUDI serves as a reference for every "reporting", for every message and for any recall.

Ismail Demiralp, together with John-Marco Fader, filled the segment “UDI practice at the manufacturer's site. The stations from the “UDI project start” to “Go Live” were carefully considered. There were tips on the composition of the project team, on building up UDI knowledge and on steps towards implementation. As a central component, this includes the necessary provision and maintenance of the data elements for both labeling and registration. According to the MDR, the UDI data must be provided regardless of the availability of the EUDAMED UDI module. With regard to UDI, it was explained that one of the central aspects is the maintenance of the technical product documentation, this also includes the generation of the BUDI (s). The report on the empirical values of DENTAURUM was extremely informative with regard to the step-by-step UDI implementation for approx. 6,700 products from marking to registration in the GUDID and about the current adaptation to the MDR.

Heinrich Oehlmann supplemented the area "around UDI" with the short report on the update of the PaperEDI standard with the inclusion of specific data elements, once especially for UDI-DI's and also for order items with patient-related parameters such as name or case number and tooth position.

John-Marco Fader closed the event after all questions had been answered, not without referring to the UDI book, 2nd edition, and thanked the participants and speakers and especially the organizer, Mr. Gregor Stock, who made this virtual event possible.

Noted 24.2.2021: Heinrich Oehlmann

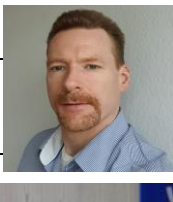
virtual

UDI-Workshop

Unique Device Identification
UDI implementation in Europe compatible to USA and the world

Program of the 28th Health Care Barcode Users Day
24.02.2021, 10:00 to 12:00, 13:00 to 15:00
Moderation by: John-Marco Fader, Chairman JWG AIDC

10:00	**Welcome to the virtual workshop,** what are the most burning topics	John-Marco Fader
10:15	**UDI LABELLING,** step by step, UDI symbols, data and label inspection (QC)	Harald Oehlmann
10:50	**UDI symbol quality control**, parameters and technical realization	Wilfried Weigelt
11:25	**UDI structured by the IFA Coding System**, the features and options	Axel Röpke
12:00	*Break*	
13:00	**UDI and EUDAMED,** Information on the UDI database, SRN, BUDI and master data	Harald Oehlmann
13:30	**UDI practice at the manufacturer's site**, UDI labeling and UDI registration recently for USA, now for EUDAMED	John-Marco Fader & Ismail Demiralp
14:30	**PaperEDI Update for UDI**	Heinrich Oehlmann
14:45	**UDI and exchange of experience** Contributions, questions from the group of participants and discussion	
14:55	**Summary** - the moderator	
15:00	End of the UDI Workshop	



Your experts: :

John-Marco Fader	Obmann G.AK AIDC, Leiter Materialwirtschaft & Logistik, Dentaurum
Gregor Stock	Referent Legal Affairs, VDDI und FIDE, Köln
Dr. Harald Oehlmann	DIN, ISO, CEN, MedTech, Leiter Technologie ELMICRON, Naumburg
Axel Röpke	Referent Informationsstelle für Arzneispezialitäten – IFA GmbH, FFM
Wilfried Weigelt	DIN, ISO und REA ELEKTRONIK, Leiter Barcodeprüfsysteme
Ismail Demiralp	Europe IT Consulting GmbH, Geschäftsführer
Heinrich Oehlmann	Senior Consultant, Eurodata Council, Den Haag

The VDDI e.V. was responsible for organizing the event.
Each speaker represented his own institution.

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