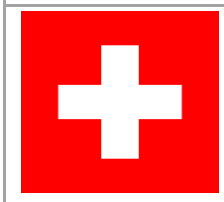
UDI World Overview July 2021

EUROPE IT Consulting GmbH

Software Development and Consulting

Authority		Database	Issuing Agencies	Current state/next deadline	Deadline
	FDA (Food and Drug Administration)	**GUDID** (Global Unique Device Identification Database)	GS1, HIBBC, ICCBBA	Class I and devices that have not been classified into class I, class II or class III must meet UDI requirements by September 24, 2022. Sources	2014 - 2022
	European Commission	**EUDAMED** (European database on medical devices)	GS1, HIBBC, ICCBBA, IFA	UDI/Device, NBs and Certificates modules released in September 2021. Playground available. Since May 26, 2021: UDI-carriers must be placed in the labels of devices Class III and Implantable. Next steps on May 26, 2023: - UDI-carriers must be placed in the labels of devices Class IIa and Class IIb. - Direct marking of the reusable devices for Implantable and Class III devices. - UDI-carriers must be placed in the labels of devices Class D (IVDR)	2021 - 2027
	Swissmedic	**Swissmedic Database**	GS1, HIBCC, ICCBBA, IFA	Considered as a third country by the EU market since May 26, 2021. Heavy and numerous consequences for manufacturers, importers, distributors. Visit our articles on the topic and the dedicated Swissmedic page.	2021 - 2027
	NMPA (National Medical Products Administration)	**MDUID** (Medical Device Unique Identification Database)	GS1 China, ZIIOT, AliHealth	Since January 1, 2021, medical devices of this first batch are required to bear UDI and data must be submitted. Compliance steps will follow for the other remaining devices. Sources	2021 - 2026
	SFDA (Saudi Food & Drug Administration)	**Saudi-DI**	GS1, HIBCC, ICCBBA	By August 1, 2021, Class D (high-risk) products must be marked, and data must be submitted. By February 2022 for Class B and C, and 2023 for Class A (Low risk). As of January 1,2022, companies will have to submit the Technical File (TFA). Sources	2021 - 2024
	MFDS (Ministry of Food & drug Safety)	**IMDIS** (Integrated Medical Device Information System)	GS1	Since July 2021, Class 2 (potential risk) devices must bear UDI. Class 1 (lower risk) will be applicable in July 2022. Sources.	2019 - 2022
	TGA (Therapeutic Goods Administration)	**AusUDID**	GS1, HIBCC, ICCBBA	Implementation in progress. UDI deadlines will be similar as in the EU. Sources	2021-2027
	Health Canada	**MDALL** (Medical Devices Active Licence Listing)	GS1, HIBCC, ICCBBA	Implementation in progress. Manufacturer are required to obtain a Medical Device Establishment License (MDEL). Main current guidance here.	2023-2030
	MHRA (Medicines & Healthcare products Regulatory Agency)	**MHRA Database**	GS1	Considered as a third country by the EU market since May 26, 2021. CE marking and certificates are accepted for the UK market until June 30, 2023. MHRA Submission deadlines are to find here. More info on our website: UDI compliance during Brexit	2021-2022