Well-Established Technologies: Updates

Question and Answer document:

A Question and Answer document is going to be prepared on Well Established Technologies under the MDR by NBCG Med (the Notified Bodies Coordination Group), along with the European Commission and other MDCG configurations. As a reminder, two delegated acts on well-established technologies (WET) under the Medical Devices Regulation were published earlier this year, and the Q&A will focus on them. Well-established technologies are relatively simple devices, with common and stable designs that don't evolve much, well-known safety and clinical performance characteristics, and a long history on the market. Members of the MDCG (such as CED) were invited to share any questions that may be considered for the Q&A document.

As information, the Q&A will be touching on, for example: Article 52(4) of the relevant delegated regulation which added devices such as bone wax, bone fillers, bone substitutes, radiography markers, transpalatal distractors, dental implants, orthodontic devices, and dental barriers to the list of those exempted from the obligation to perform an assessment of the technical documentation for every single device
Article 61 (6b) of the relevant delegated regulation, listing the devices exempted from the obligation to perform clinical investigations, e.g. sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, connectors.

The WG DMMD prepared a set of proposed questions which were submitted by the deadline, the CED office will provide further updates when available.

ANDI Request:

The Italian dental association ANDI has asked for support for the recognition of dental abutments and haemostatic sponges as Well-Established Technologies (WET) under the proposed revision of the Medical Devices Regulation (MDR). ANDI's principal objective is not, however, the usual benefit associated with WET status (a more proportionate approach to clinical evidence for technologies with a long-established safety and performance). ANDI wants to use WET recognition to argue that these devices should benefit from relief from certain Unique Device Identification (UDI) requirements, in particular requirements that result in dental practices having to register, store or retain UDI information.ANDI states that these are widely used and well-understood technologies for which the administrative burden associated with UDI requirements may be disproportionate.

In its proposal from December 2025 on the MDR, the Commission proposes to amend Article 27(11) MDR to empower it to determine that certain UDI-related obligations under Article 27, Article 29 and Annex VI Part C should not apply to particular devices. The UDI system encompasses not only assignment and labelling of UDI by manufacturers, but also storage of UDI information by health institutions and healthcare professionals under the conditions established by Article 27. The proposed amendment *could* offer more proportionate UDI requirements for particular categories of dental devices.

Important distinction concerning WET status: The proposed amendment to Article 27(11) does not identify WET status as a criterion for obtaining a UDI exemption. Nor would classification as WET automatically exempt a device from UDI requirements. ANDI considers that that recognition as WET would demonstrate that dental abutments and haemostatic sponges have characteristics such as long-standing clinical use, a well-established safety profile and well-understood risks. Those characteristics could then offer further support for the case for the Commission to use the updated Article 27(11) powers to grant an appropriate UDI exemption (of course, this is not yet applicable, since the file is currently in negotiations): therefore, WET status would provide supporting evidence for a subsequent UDI exemption request but the exemption itself would still need to be separately justified.

In addition to that, ANDI's principal concern is on the administrative burden on dental practices of storing and retaining UDI records, whereas the burden that the Commission proposal refers to is the financial and administrative burden for the assignment of UDI.

Next steps (if the Board agrees): It would be useful to establish precisely which UDI obligations ANDI wishes to see removed and if and whether the proposed Article 27(11) can be used for such purpose.