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Answer given by Mr Várhelyi
on behalf of the European Commission
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Regulation (EU) 2017/745 on medical devices¹ (MDR) defines ‘custom-made devices’ in Article 2(3) and provides for legal exceptions for certain mass-produced devices. Accordingly, it would depend on the specific case whether clear aligners – also known as invisible braces – may be actually considered as custom-made devices or rather mass-produced devices.

The Medical Device Coordination Group (MDCG) established under Article 103 of the MDR endorsed the guidance document ‘MDCG 2021-3 Questions and Answers on Custom-Made Devices & considerations on Adaptable medical devices and Patient-matched medical devices’² where ‘orthotic braces’ are mentioned as examples of ‘mass-produced adaptable medical devices’, not considering them as custom-made devices. This reflects the situation on the market, where the use of clear aligners is largely extended as adapted devices from mass-produced devices, as well as the views of other international regulatory frameworks^{3,4}.

Both custom-made devices and mass-produced adaptable medical devices need the prescription of authorised healthcare professionals with respect to their specific characteristics and the needs of patients. Therefore, the possibility to purchase clear aligners or invisible braces without consulting a healthcare structure or professional may indeed represent a risk for patients as well as a competitive disadvantage for healthcare manufacturers and professionals. The responsibility for market surveillance and vigilance on the appropriate placing on the market and use of those devices belongs to the national competent authorities of the Member States in the field of medical devices⁵.

¹ OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>

² https://health.ec.europa.eu/document/download/385d7e20-d8b5-49d0-abd7-8daf269bf1b8_en?filename=mdcg_2021-3_en.pdf

³ For instance, the Australian Therapeutic Goods Administration considers aligners as ‘patient-matched medical devices’, not custom-made devices. See <https://www.tga.gov.au/resources/guidance/understanding-personalised-medical-devices-rules-including-3d-printed-devices#patientmatched-medical-devices>

⁴ See the guidance on ‘Personalized Medical Devices (PMD)’ by the International Medical Device Regulatory Forum (IMDRF) <https://www.imdrf.org/working-groups/personalized-medical-devices>

⁵ https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en#national-competent-authorities