	Original Art 5.5 as mentioned in the IVDR 2017/746	Revised Art 5.5 as proposed in 2025/0404 (COD)	Additional remarks in 2025/0404 (COD)
Art 5.5. a	The devices are **not transferred** to another legal entity;	The devices are **not transferred** to another legal entity, **except** to another health institution **in the duly justified interest of public health, patient safety or patient health, or to prepare or respond to a public health emergency .**	• In the case of a transfer of the device to another health institution, the transferring and receiving health institutions **shall ensure traceability of the device**. • The receiving health institution **shall report any incident** related to the device to the transferring health institution. • This paragraph **shall also apply** to devices manufactured and used within a laboratory that is established in the Union and provides consistent, state of the art testing services for clinical research, provided those devices are intended exclusively for use in the framework of a **clinical trial subject to Regulation (EU) No 536/2014** of the European Parliament and of the Council*.
Art 5.5.c	The laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation	The laboratory of the health institution is compliant with standard EN ISO 15189 or, where applicable, national provisions for **quality and competence in medical laboratories**, including national provisions regarding accreditation	
Art 5.5.d.	The health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an **equivalent device** available on the market;	**DELETED!**	
Art 5.5.e.	The health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;	Upon request by a **competent authority**, the health institution provides information on the use of such devices to its competent authority, which shall include the justification referred to in point (a)	
Art 5.5.f.(i.i.i)	A declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor	A declaration either that the health institution is accredited to the standard referred to in point (c) or that the devices meet the relevant general safety and performance requirements set out in Annex I and, where applicable, information on which requirements are not fully met with a **reasoned justification** therefor;	
Art 5.5.g.	As regards class D devices in accordance with the rules set out in Annex VIII, the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met. Member States may apply this provision also to class A, B or C devices in accordance with the rules set out in Annex VIII	As regards class D devices in accordance with the rules set out in Annex VIII, where the health institution is not accredited to the standard referred to in point (c), the health institution draws up **documentation sufficiently detailed** to enable the competent authority to ascertain that the relevant general safety and performance requirements set out in Annex I are met;	
Art 5.5.h.	The health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (g);	**DELETED!**	