



Komorniki, 20.05.2022

STATEMENT IN VITRO DIAGNOSTIC MEDICAL DEVICES

The in vitro medical devices offered by Noex Sp. z o.o. J. have been lawfully placed on the market under the Directive 98/79/EC and did not require the participation of a notified body in the conformity assessment procedure.

The medical devices have a declaration of conformity issued before 26 May 2022.

According to Regulation (EU) 2022/112 of the European Parliament and of the Council of 25.01.2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices, where the conformity assessment procedure will require the participation of a notified body on the basis of the above mentioned Regulation, they may be placed on the market or put into service until 26.05.2027. This applies to Class A devices placed on the market in a sterile condition.

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Wspólnik

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