Annex 28
to the Procedure for Conducting Expert Evaluation of Registration Materials Pertinent to Medicinal Products Submitted for the State Registration (Re-Registration) and for Expert Evaluation of Materials about Introduction of Changes to Registration Materials during the Validity Period of Registration Certificate (item 4 section IV)

CERTIFICATE OF COMPLIANCE FOR PLASMA MASTER FILE

№ \_\_\_\_\_\_\_\_\_\_

Certificate of compliance for plasma master file has been issued based on results of positive expert evaluation of PMF conducted by the State Expert Center of MoH.

The validity period of PMF is unlimited.

Certificate of compliance for plasma master file remains valid until the re-evaluation of PMF is conducted according to the established requirements.

Applicant and his location \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Period of data collection \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

List of plasma derived medicinal products pertinent to which a certificate of compliance for plasma master file has been issued \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Date of issue \_\_\_\_\_ \_\_\_\_\_ 20\_\_\_

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(position) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(signature) | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(last name, initials) |

{Procedure amended by new annex 28 according to MoH Ukraine Order № 1528 of 27.06.2019 }