EU DECLARATION OF CONFORMITY

issued under the sole responsibility of the manufacturer

with involvement of Notified Body no. 2797 BSI, addressed as BSI Group the Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands.

In conformity with Regulation (EU) 2017/746 of the European Parliament and of the Council on *in vitro* diagnostic medical devices (hereinafter referred to as IVDR)

MANUFACTURER

SRN: CZ-MF-000024067

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, Czech Republic

Hereby declare, that the *in vitro* diagnostic medical device

HEPTAPHAN

Classification:	Class B, rule 6 per Annex VIII of IVDR
Catalogue number:	URPH0013, URPH0014
Basic UDI-DI:	8592156UTMA0201BA
Intended Use:	Diagnostic strips for in vitro visual semiquantitative determination of pH, protein, glucose, ketones, urobilinogen, bilirubin and blood in urine. Intended for screening and monitoring of acidosis / alkalosis, proteinuria, glucosuria, ketonuria, urobilinogenuria, bilirubinuria and haematouria. For professional use at clinical laboratories only. The semiquantitative analysis is not sufficient for the completing of diagnoses.

complies with the essential requirements of IVDR Annex I.

Compliance has been assessed in accordance with the procedure of Annex IX (I, III) of IVDR.

Certificate number: IVDR 745525
Group: IVR 0608

In Brno, date 26.09.22

Erba Lachema s.r.o.
Karásek 2219/1d, 621 00 Brno
D.Č.: CZ26918846 -26-

Ing. Michaela Miklová
Associate RA Manager