

# 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

## PENTAPHAN

**Classification:** Class B, rule 6 per Annex VIII of IVDR

**Catalogue number:** URP0010

**Basic UDI-DI:** 8592156UTMA0201BA

**Intended Use:** Diagnostic strips for *in vitro* visual semiquantitative determination of pH, protein, glucose, ketones and blood in urine. Intended for screening and monitoring of acidosis / alkalosis, proteinuria, glucosuria, ketonuria and haematuria. 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

26.09.2015

**Erba Lachema s.r.o.**  
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