In Prague, 25th August 2025

Subject: **eSens EC certificate not issued according to EU directive**

We hereby confirm that the medical devices offered in the eSens product line comply with the relevant legislation, as they are in vitro diagnostic devices that have been assessed for conformity in accordance with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Since these products are not listed in List A or List B of Annex II to the above-mentioned Directive, nor are they intended for self-testing, their conformity assessment was not carried out by a notified body and therefore no EC certificate was (or could be) issued.

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