



Certificate of EU product notification

Herewith we confirm that

MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7
66386 St. Ingbert
Germany

has taken over the function of an European Authorized Representative according to the requirements of Article 11 of the MDR (EU) 2017/745 for

i-SENS, Inc.
43, Banpo-daero 28-gil, Seocho-gu,
Seoul 06646,
Republic of Korea

MT Promedt Consulting GmbH has made the product notification at the relevant competent authority.

The medical devices of the manufacturer, covered by the notification, are listed in Annex I of this certificate.

This certificate does not attest the conformity of the medical devices with the above mentioned directive. The conformity is stated in the respective product-related Declarations of Conformity signed under the sole responsibility of the manufacturer.

12.04.2024

Christoph Leder
- Managing Director -

Enclosure
Annex I



i-SENS, Inc.

Annex I

to "Certificate of EU Product Notification"

(List of CE marked Products)

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Product Name (Model name)	Registration Number (at the German CA/DIMDI)
CareSoft Lancing Device	DE/CA70/00031289
Tempo Lancing Device	DE/CA70/00031289
NIPRO Premier Lancing Device	DE/CA70/00031289
AUTOCHECK GluCare Lancing Device	DE/CA70/00031289
CareLance Lancing Device	DE/CA70/00031289
alphacheck professional Lancing Device	DE/CA70/00031289
emVia Lancing Device	DE/CA70/00031289
CareSens Air CGM System	DE/CA70/00200802
Sens365	DE/CA70/00200803



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12.04.2024

Christoph Leder
- Managing Director -

