CE *Declaration of Conformity*

MANUFACTURER:	**i-SENS, Inc.** **43, Banpo-daero 28-gil, Seocho-gu,** **Seoul 06646, Korea**
EUROPEAN REPRESENTATIVE:	**Medical Technology Promedt Consulting GmbH** **Altenhofstrasse 80** **66386 St. Ingbert, Germany**
PRODUCT:	**Lancing Device**
MODEL:	**alphacheck professional Lancing Device**
CLASSIFICATION:	**Class I according to the Rule 1 of Annex VIII of the Regulation (EU) 2017/745**
CONFORMITY ASSESSMENT ROUTE:	**Annex IV of Regulation (EU) 2017/745**

We herewith declare under our sole responsibility of the manufacturer that the above-mentioned product meets the provisions of the Regulation (EU) 2017/745. All supporting documentation is retained at the premises of the manufacturer.

STANDARD APPLIED:	**See List of Applied Standards**
START of CE-MARKING:	**2013-07-25**
DATE OF ISSUE:	**2021-05-21**
SIGNATURE:	

CEO
Geun Sig Cha

Declaration of Conformity, Attached 1

List of Applied Standards

Document Number	Title of Document
EN ISO 13485:2016	Medical devices - Quality management systems -Requirements for regulatory purposes
ISO 14971:2019	Medical devices - Application of risk management to medical devices
IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
ISO 10993-1:2018 EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process