Declaration of Conformity

Manufacturer's Name: **OSANG Healthcare Co., Ltd.**

Address: 132, Anyangcheondong-ro, Dongan-Gu
Anyang-si, Gyeonggi-do, 14040, Republic of Korea
Tel.: +82-31-460-0300 Fax: +82-31-460-0401

EC-Representative: **Obelis S.A.**

Address: Bd. Général Wahis 53,
1030 Brussels, Belgium

Declares that the product:

Product: **Sterile Lancets**
infopia® (ILT-00002)

Classification: **Class IIa by Rule 6 of Annex IX, MDD 93/42/EEC amended by 2007/47/EC**
(All surgically invasive devices intended for transient use are in Class II a unless they are)

Conformity assessment Route: **Annex V of council directive 93/42/EEC**

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer and manufacturer is exclusively responsible for the declaration of conformity.

Notified Body : **TÜV SÜD PRODUCT SERVICE GmbH**
Ridlerstr. 65, 80339 München, Germany

ID/Number of Notified Body: 0123

Number of EC Certificate	**:**	**G2 001395 0011 Rev.00**
Date of Issue	**:**	**22 October 2018**
Place	**:**	**Anyang-si, Korea**
Valid From	**:**	**31 January 2019**

Attachment #1. Products, Attachment #2. List of applicable standards

Signature: _____

Dong Hyun, Lee

CEO of OSANG Healthcare Co., Ltd.

Attachment #1. Products

Sterile lancets

[General Lancets]

1) 28G
2) 30G

Attachment #2. List of applicable standards

No.	Title of standards	Contents
1	**EN ISO 13485:2016**	Quality system-Medical devices-Particular requirements for the application of ISO 9001
2	**EN ISO 14971:2012**	Medical devices – Application of risk management to medical devices
3	**EN 1041:2008**	Information supplied by the manufacturer with medical devices
4	**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
5	**EN ISO 10993-1:2009**	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
6	**EN ISO 10993-5:2009**	Biological evaluation of medical devices – Part 5 : Tests for in vitro cytotoxicity.
7	**ISO 10993-10:2010**	Biological evaluation of medical devices – Part 10 : Tests for irritation and skin sensitization
8	**EN ISO 11137-1:2015**	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
9	**EN ISO 11607-1:2009**	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
10	**EN ISO 11607-2:2006**	Packaging for terminally sterilized medical devices Validation requirements for forming, sealing and assembly processes
11	**EN ISO 14644-1:1999**	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness
12	**ISO 14644-2:2000**	Cleanrooms and associated controlled environments — Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
13	**EN ISO 14644-3:2005**	Cleanrooms and associated controlled environments-Part3: Metrology and test methods
14	**MEDDEV 2.7.1 :2016**	Clinical Evaluation