

EC - DECLARATION OF CONFORMITY

Product Identification

Common name: Gene expression profiling test system for breast cancer prognosis
Product name: OncoFREE
Class: General (Others)

Manufacturer

Company name: DCGEN Co., Ltd.
Address: #902, 130 Sajik-ro, jongno-gu, Seoul, 03170, Korea
Representative: Woosung Chung / Quality Management Representative

EC Representative

name: JaviTech e.k
Address: Sachsenhausener Str. 16, 65824, Schwalbach a. Ts., Germany

Conformity Assessment


DCGEN Co., Ltd. Declares that the above-mentioned products meet the provision of the Directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.

Council Directive 98/79/EC	In vitro diagnostic medical devices
EN ISO13485:2016	Medical devices-Quality management systems
BS EN ISO 18113-1:2011	In vitro diagnostic medical devices-information supplied by the manufacturer(labelling)-part1: definitions and general requirements
BS EN ISO 18113-2:2011	In vitro diagnostic medical devices-information supplied by the manufacturer(labelling)-part2: In vitro diagnostic reagents for professional use
BS EN ISO 14971:2019	Medical devices-Application of risk management to medical devices
BS EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
BS EN 23640:2015	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
EN ISO 15223-1:2016	Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied-Part1: General requirements
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents



Company Representative: Woosung Chung

Title: Director / Quality Management Representative

Signature: 

Date: 2020. 05. 11