

Manufacturer's Self Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service.

We, as Manufacturer:

NSK Europe GmbH.
Elly-Beinhorn Straße 8
65760 Eschborn
Germany
SRN: DE-MF-00007039

Notified Body:

BSI Group The Netherlands B.V
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Netherlands

Notified Body number:

2797

MDD Certificate Registration No:

CE 623882

Original Expiry Date:

May 26th 2024

Declare under our sole responsibility that:

- The devices listed below continue to comply with the Medical Device Directive 93/42/EEC.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health
- The MDD EC certificate covering the devices was valid after May 26th 2021 and have not been suspended nor withdrawn afterwards
- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- Requirements of regulation (EU) 2017/745 relating to post-market surveillance and registration of economic operators are met.
- Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.

This declaration applies for the Products listed below:

Medical Device

Brand name: iCare+

Classification

Following MDR 2017/745 annex VIII, Rule 16:

Class IIb

EMDN Description:

Cleaning and disinfection equipment

EMDN Code:

Z12011301

Variant	Product code	UDI-DI	Base UDI-DI
iCare+ C2	S102001	04560264538993	45606453S10X001XL
iCare+ C3	S103001	04560264539020	45606453S10X001XL

Eschborn, Germany: February 22th 2024

Name:

Peter MESEV

Function:

General Manager

Signature:

NSK Europe GmbH