

EC DECLARATION OF CONFORMITY

We as Manufacturer:

**NSK Europe GmbH.
Elly-Beinhorn Straße 8
65760 Eschborn
Germany**

SRN: DE-MF-00007039

Declare under our sole responsibility that the Products listed below, and to which this declaration relates conforms to the essential requirements of the following directives:

- Directive 93/42/EEC
- Directive 2006/42/EC
- Directive 2014.30.EU
- Directive 2014.35/EU
- Directive 2012.19/EU
- Directive 2011/65/EU ⁽¹⁾

Note ⁽¹⁾: RoHS without involvement of the notified body

Medical Device Group name:

Automatic Reprocessing devices

Classification following 93/42/EEC annex IX, rule 15:

Class IIb

Name of the product	Variant	Product code	Basic UDI-DI	CND Code	GMDN Code
iCare+	C2	S102001	456026453899CA	Z12011301	34074
iCare+	C3	S103001	456026453902B6	Z12011301	34074

This Declaration of Conformity is based on the EC Directive 93/42/EEC Annex II, excluding Section 4 under the supervision of BSI

Notified Body:

BSI Group The Netherlands B.V

Benannte Stelle:

**Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Netherlands**

Notified Body number:

2797

EC Certificate Registration No:

CE 623882

This Declaration of Conformity is valid until: **May 26th 2024**

Eschborn, Germany: June 26th 2021

Name:

Peter MESEV

Function:

General Manager

Signature:



NSK Europe GmbH

Elly- Beinhorn-Strasse 8, D-65760 Eschborn, Germany, Tel. ++ 49 (0)6196 77 606-0, Fax ++ 49 (0)6196 77 606-29
Bankverbindung: Frankfurter Sparkasse, IBAN : DE23500502010200305697, BIC : HELADEF1822
Geschäftsführer : Ing. P. Mesev, Haruo Yokoyama, Kazuhiko Nakazawa, AG Ffm, HRB 56583, Steuer-Nr. 043 240 37564
info@nsk-europe.de, www.nsk-europe.de