

EC DECLARATION OF CONFORMITY

We as Manufacturer:

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

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 2006/43/EC
- Directive 2011/65/EU ⁽¹⁾

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

Medical Device Group name:
Classification following 93/42/EEC annex IX, rule 15:

Automatic Reprocessing devices
Class IIb

Name of the product	Variant	Product code	UDI	UMDNS
iCare+	C2	S102001	4560264538993	11-278
iCare+	C3	S103001	4560264539020	11-278

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:
Benannte Stelle:

BSI Group The Netherlands B.V.
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:

July 14th 2020

Eschborn, Germany: April 1st 2019

Name: Peter MESEV

Function: General Manager

Signature:

