Declaration acc. to Article 12 – MDD

according to Council Directive 93/42/EEC issued under the sole responsibility of the manufacturer

Procedure Pack Producer	**Sengewald Klinkprodukte GmbH** Adlerstraße 2 83101 Rohrdorf-Thansau Germany
This Declaration is valid for the following medical devices	Product family 10 Custom Procedure Trays Brand name: Secutray
Conformity assessment procedure	Annex V of Directive 93/42/EEC
CE-marking	n/a
EC Certificate	EC certificate number G2S 025197 0016 Rev. 00 Expiry date: 2024-05-26
Notified Body	TÜV SÜD Product Service GmbH

We herewith declare that the products to which this declaration relates are in compliance with the requirements set out in the Council Directive 93/42/EEC, amended by Council Directive 2007/47/EEC and as transposed into National law. The products above are subject to a certified Quality Management System under supervision by a certification body.
The individual medical devices are used within their intended purpose and within the limits of use specified by their manufacturer. The mutual compatibility of the medical devices in accordance with the manufacturer's instructions has been verified and the operations have been carried out in accordance with these instructions.
Relevant information to users and relevant instructions from the medical device manufactures are included in the documents accompanying the device.
The assembly operations including packaging and sterilization are subjected to appropriate methods of internal control and inspection and are carried out under a quality system complying with the requirements of Annex V of MDD.
This statement is valid in connection with the release of document for the respective batch of produced devices.

EU Art. 12 MDD Statement	**Place and Date**	**Approval by**
DOC-10-01	Rohrdorf, 22. July 2022	Augusto Orsini (CEO) **Signature**