

EC - Declaration of Conformity

This Declaration of Conformity is drawn up by First15 B.V. for the Personal aid kit in accordance with article 22 of the Medical Devices Regulation (EU) 2017/745.

COMBINER OF THE PROCEDURE KIT

Company name: First15 B.V.
Full address: Laan van Kronenburg 14
Postal code: 1183 AS
Place: Amstelveen
Country: The Netherlands

PROCEDURE PACK

Basic UDI - DI 87202994175F15PAK5L
Generic name: Personal aid kit
Life Saving Kit
Only contains CE marked devices: Yes
Procedure pack is sterilized: No
Procedure pack incorporates the following devices:
Tourniquet
Nitrile gloves
Emergency bandage
Breathing mask
Rescue blanket

First15 B.V. has verified the mutual compatibility of the devices incorporated in the procedure pack in accordance with the manufacturers' instructions and has carried out the activities in accordance with those instructions.

First15 B.V. has packaged the procedure pack and supplied the relevant information to users incorporating the information to be supplied by the manufacturers of the devices which have been put together.

The activity of combining devices as a procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

Place: Amstelveen

Name: M. Van der Wilt

Function: Managing Partner

Tel: +31 6 39 76 53 58

Date: 16-06-2023

Signature:

