



EC DECLARATION OF CONFORMITY

Basic UDI Nr : 5415174120303StephanieXN

Actor ID/SRN : BE-MF-000019750

The manufacturer:

VERMEIREN GROUP

Address :

Vermeirenplein 1/15

2920 Kalmthout

Belgium

declares under his sole responsibility that the CE marked devices :

Product group: Elbow crutches

Intended purpose: Devices providing support when walking that have a semi-circular support for the elbow, a horizontal hand grip, a single shaft, and one tip (ferrule). (WHO ICF: d450, d460, d469, d498, d499)

ISO 9999: 12 03 06

EMDN: Y12030601

Brand: Vermeiren

Type: Stephanie

have been classified as class I, according to annex VIII (EU) MDR 2017/745, rule 1,

and is manufactured in full conformity with the European regulations and/or directives below - including the latest modifications - and with the national law, that organizes these directives:

MDR (EU) 2017/745

and is in conformity with the following international standards:

EN ISO 21856:2022, EN1985:1999, ISO 11334-1:2007

City, Date: Kalmthout, 2024-03-04

Signature:

Name: Patrick Vermeiren

Function: CEO

VERMEIREN Group N.V.

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Certified ISO 13485