

## EC DECLARATION of CONFORMITY

# Regulation (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices

We, MOBILEX A/S
Registered place of business
Grønlandsvej 5
8660 Skanderborg
Denmark



SRN: DK-MF-000021885

Hereby declare under our sole responsibility as a legal manufacturer that the product specified on the product list below, meet the essential health and safety requirements and is in conformance with the provisions of the Regulation (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices.

The product specified on the product list below is "technical aid for the disabled", classified as Class I, medical device. The classification is based on the requirements of Rule 1 of annex VIII, of the Regulation (EU) 2017/745.

The CE marking has been affixed on the product according to Annex V of the Regulation (EU) 2017/745.

#### **PRODUCT LIST**

#### Impala Rollator:

REF / item no.	312060	312061	312062
UDI-DI	5740001403077	5740001403084	5740001403091
BASIC-UDI-DI	57400014IMPALABV		

### **ACCESSORIES LIST**

Item nr.	Accessories item nr.
312060, 312061 & 312062	312073

Harmonized norms used during conformity estimation:

PN-EN ISO 11199-2:2005, EN ISO 14971:2012, EN 1041:2009

Skanderborg, 2022-04-05, Thomas N. Christensen, Managing Director

Issued: 2022/04