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.

Intended purpose: designed to increase the mobility of persons who have difficulties standing or walking

PRODUCT LIST

Leopard Rollator:

REF / item no.	312300	312301	312303	312304	312309
UDI-DI	5740001411058	5740001411065	5740001411089	5740001411096	5740001411140
BASIC-UDI-DI	57400014LEOPARDF6				

ACCESSORIES LIST

Item nr.	**Accessories item nr.**
312300+01+03 +04+09	312340, 312315, 312320, 312321, 312322, 312325, 312329, 312355, 312332, 312347, 312364, 312365, 312368, 31236A, 31236B

Harmonized norms used during conformity estimation:
PN-EN ISO 11199-3:2005; EN ISO 14971:2012, EN 1041:2009

Skanderborg, 2022-05-18, Thomas N. Christensen, Managing Director

Issued: 2022/05