EU DECLARATION OF CONFORMITY

The manufacturer
BANO AS
Having registered place of business given as
Industrivegen 22
6823 Sandane
Norway

declares under its sole responsibility that the Medical Device further identified by

Basic UDI-DI given as: 709006695800019K8

Product Name: Bano turnable bed
Product Code: 800019

which intended purpose is
to provide adjustable support and positioning for patients in healthcare settings, enhance patient's comfort, and facilitate medical care

belonging to Risk Class I in accordance with Rule 13 set out in Annex VIII
to (EU) 2017/745 Regulation

is in conformity with provisions of
(EU) 2017/745 Regulation
and with the provisions of
2006/42/EC Directive
2014/35/EU Directive
2011/65/EU Directive

The conformity is declared in relation to the application of the relevant sections of the following standards
ISO 13485:2016
ISO 14971:2019
EN 60601-1:2006+A1:2013 - on all Electronic Components
EN 60601-1-2:2015 – on all Electronic Components and related parts and accessories
EN 60601-1-2:2015 + A1:2020 – on full assembled Medical Device
[Requirements – Test: Radiated Emission (Below 1GHz)]
NEK IEC 60601-2-52:2009+A1:2015 - except for 201.9.1.101 / 201.9.2.2.2 / 201.9.101
NS-EN ISO 10993-18:2020+A1:2023
NS-EN ISO 10993-1:2020
ISO 17664-2:2021
ISO 15223-1:2021
EN IEC 63000:2018

Sandane 28.01.2025

Signatory Trude Bruland CFO Bano AS