EU DECLARATION OF CONFORMITY

Manufacturer:	
Manufacturer name (company):	**Lifeness AS**
Post address	Vestregate 33
Postcode and city,	9008 Tromsø,
Country	Norway
Email	contact@lifeness.io
Website	https://lifeness.io
Organization number	921141130
Authorized Representative	Lifeness GmBh, Ulanenweg 11, 14469 Potsdam, Germany Company number: HRB 38122
SRN (Single Registration Number)	pending

Medical Device:	
Product name:	**Wellapy** *(software application)*
Basic UDI-DI	709006306Wellapy630HB
UDI-DI	17090063060042
Model/Version	6.3.0
Product Category	Digital Therapeutic (DTx)
Description	A digital therapeutics application for obesity treatment for personalized weight management with nutrition, exercise, and behavioral therapy
Intended purpose	Software for obesity management via behavioral, nutrition and exercise programs
Risk Classification	Class I *(non-invasive software, MDR Annex VIII Rule 11)*
Forward current	France
Notified Body:	N/A (Class I self-declared device)

Lifeness AS, under its sole responsibility as manufacturer, declares that Wellapy version 6.3.0 is a Class I medical device (Rule 11, Annex VIII) in conformity with Regulation (EU) 2017/745 on medical devices. Conformity is demonstrated via compliance with the MDR and the standard/specifications listed in Annex A (see page 2)

Place Fjellhamar,
Date 21. May 2025

Signed for and on behalf of
Lifeness AS by

Solvor Øverlien Magi
CEO

Lifeness.io

Annex A - References

Under our sole responsibility, we verify that the device Wellapy (v6.3.0, Basic UDI-DI 709006306Wellapy630HB) conforms with Regulation (EU) 2017/745 on medical devices.

Standards

- **Regulation (EU) 2017/745** – *MDR (Medical Device Regulation)*
- **EN ISO 13485:2016** – *Medical devices – Quality management systems – Requirements for regulatory purposes (Harmonized)*
- **EN ISO 14971:2019** – *Medical devices – Risk management (Harmonized)*
- **EN IEC 62304:2006/A1:2015** – *Medical device software – Software life cycle processes (Harmonized)*
- **EN IEC 62366-1:2015/AC:2016** – *Medical devices – Part 1: Application of usability engineering (Harmonized)*
- **IEC 82304-1:2016** - *health software safety standard (Harmonized)*
- **ISO/IEC 27001** *applied standards*
- **ISO 17100:2015** - *Translatio snervices (Harmonized)*