LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

2021-02-15 Diarienummer: 6.6.1-2021-13121

Registreringsbekräftelse / Confirmation of registration

Företagsnamn / Company name:	Zoomability AB
Organisationsnummer / Company registration number:	556850-2206
Utdelningsadress / Address:	Brandthovdagatan 24 72135 Västerås Sverige
Eudamed-registreringsnummer / SRN:	-

Registrering enligt förordning (EU) 2017/745 (MDR) om medicintekniska produkter, förordning (EU) 2017/746 (IVDR) om medicintekniska produkter för in vitro-diagnostik, Läkemedelsverkets föreskrifter (LVFS 2003:11) om medicintekniska produkter, Läkemedelsverkets föreskrifter (LVFS 2001:5) om aktiva medicintekniska produkter för implantation och/eller Läkemedelsverkets föreskrifter (LVFS 2001:7) om medicintekniska produkter för in vitro-diagnostik

Zoomability AB intygar i och med att de registrerar sin verksamhet hos Läkemedelsverket att de fullgör sina skyldigheter i enlighet med tillämpliga krav i gällande förordning(ar)/föreskrift(er).

Registreringen avser roll: Tillverkare av CE-märkta produkter

Registration according to Regulation (EU) 2017/745 (MDR) on medical devices, Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices, the Swedish Medical Products Agency's Regulations (LVFS 2003:11) on medical devices, the Swedish Medical Products Agency's Regulations (LVFS 2001:5) on active implantable medical devices and/or the Swedish Medical Products Agency's Regulations (LVFS 2001:7) on in vitro diagnostic medical devices

Zoomability AB declares by registering their business at the Swedish Medical Products Agency that they fulfil their obligations in accordance with applicable requirements in existing Regulation(s).

The registration relates to actor role: Manufacturer of CE marked devices

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Webbplats: www.lakemedelsverket.se E-post: registrator@lakemedelsverket.se

Identification of the Legal Manufacturer:	Zoomability AB Brandthovdagatan 24 721 35 Västerås Sweden
Identification of Authorized Representative:	EC REP Zoomability AB Brandthovdagatan 24 721 35 Västerås Sweden
This Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer.	
Identification of the device(s) concerned:	Zoom Uphil 2021
Risk Classification:	Class I
We hereby declare that the above-mentioned devices comply with the Medical Device Regulation (EU) MDR:2017/745C for medical devices.	
Identification of the person authorized to sign on behalf of Legal Manufacturer:	Name: Pehr Johan Fager Signature: Title: CEO Place of Issue: Västerås Date:

Revision History

Rev	*Date mm/dd/yy*	*DCN*	*What changed?*	*Why did it change?*	*Author*
1	2021/01/29	ZOOM029 DoC MDR	First release certified product of Zoom as medical device MDR Class I	Product self-declared for release as medical device MDR Class I to the market	C Hermansson