

# PhysioVR system

## DECLARATION required by article 22 of MDR

Responsible for placing the system on the market :	<b>VIRTUALIS</b>
Name of the product(s) concerned:	<b>PHYSIOVR</b>
Reference of the product(s) concerned:	See Appendix 1
Technical file reference:	Q-REC-VI-74_Demonstration of conformity of Virtualis systems with requirements of article 22 of the European Medical Device Regulation 2017/745

This declaration applies to the system **PHYSIOVR** composed of the components listed in Appendix. Each of these devices bears the CE marking and is used within its intended purpose and within the limits of use specified by its manufacturer.

VIRTUALIS states that the mutual compatibility of the devices in accordance with the manufacturers' instructions has been verified and that the operations have been carried out in accordance with these instructions.

VIRTUALIS states that the system has been packaged and that relevant information incorporating relevant instructions from the manufacturer has been supplied to users.

VIRTUALIS states that its whole activity to put the system **PHYSIOVR** on the market is subjected to appropriate methods of internal control and inspection.

According to article 22 of the medical devices regulation 2017/745, this declaration will be kept at the disposal of the competent authorities for at least ten (10) years after the last system has been placed on the market. The products of the system do not bear an additional CE marking and are accompanied by the information referred to in section 23 of annex I of the medical devices regulation.

Name : FRANCK ASSABAN      Function : CEO

Validity period : 10 years

Stamp, date and signature :

05/11/2025

**VIRTUALIS**

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### APPENDIX 1: LIST OF REFERENCES COVERED BY THE DECLARATION

Software	Platform	Option	Pack PC	Pack VR	Reference
PhysioVR Access			Desktop	Focus	PA-0-D-F
PhysioVR Access			Laptop	Focus	PA-0-L-F
PhysioVR Access			Desktop	Pro2	PA-0-D-P
PhysioVR Access			Laptop	Pro2	PA-0-L-P
PhysioVR Access	force measuring platform	Smart	Desktop	Focus	PA-S-D-F
PhysioVR Access	force measuring platform	Smart	Laptop	Focus	PA-S-L-F
PhysioVR Access	force measuring platform	Smart	Desktop	Pro2	PA-S-D-P
PhysioVR Access	force measuring platform	Smart	Laptop	Pro2	PA-S-L-P
PhysioVR Access	dynamic posturography platform	Premium	Desktop	Focus	PA-P-D-F
PhysioVR Access	dynamic posturography platform	Premium	Laptop	Focus	PA-P-L-F
PhysioVR Access	dynamic posturography platform	Premium	Desktop	Pro2	PA-P-D-P
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PhysioVR Access	dynamic posturography platform	Premium +	Desktop	Focus	PA-P+-D-F
PhysioVR Access	dynamic posturography platform	Premium +	Laptop	Focus	PA-P+-L-F
PhysioVR Access	dynamic posturography platform	Premium +	Desktop	Pro2	PA-P+-D-P
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### Appendix 2 :List of components

Products	Medical device (yes/no)	Declaration of conformity
PhysioVR	Yes	DCEC_PhysioVR_Rev01
Desktop or Laptop computer	No	NA
Screen	No	NA
Wired VR headset	No	2qal100_CE declaration headset Vive pro 2
Wireless VR headset	No	2qbb100_ce_declaration (XR Elite) 2qd4100_Headset Focus vision_CE declaration
VR Base stations (for wired headset)	No	NA
Wi-Fi router only (for wireless headset)	No	GL.iNet - EU Declaration of Conformity - GL-MT3000
Camera (leap motion)	No	UL-006711-RC-2-EU Declaration of Conformity leap motion controller 2
VR controllers	No	2pr7200_CE declaration_Vive controller
VR trackers	No	2qab100_CE declaration_Vive tracker 2qbp100_ce
Steering wheel	No	DoC_en_4160781_T128-P EMEA - TYPE C (PLUG EU)_2022
Cart	No	NA
Camera support	No	NA
Straps	No	NA
Clamp for VR tracker	No	NA
Headgear for VR tracker	No	NA

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Products	Medical device (yes/no)	Declaration of conformity
Foot switch	No	NA
Remote controller (XBOX wireless controller)	No	EU_DoC_1914_062122_XBOX wireless controler
Force measurement platform	Yes	CE updated 20200331
Foam frame	No	NA
AIREXBalance cushion	Yes	20240405_DeclarationofConformity_AIREXBalance-Trainer

