Manufacturer	apoQlar GmbH
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Telephone Number	+49 (0) 40 24 192 779
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Web page	https://apoqlar.com/
Product, Version, and Intended Use	VSI HoloMedicine®– v 2.0.0 VSI HoloMedicine is a software device for displaying medical images and allowing the visualization of 3D imaging holograms outside and/or inside the surgical room. VSI HoloMedicine is indicated for use by qualified healthcare professionals, including but not restricted to surgeons, radiologists, physicians, and technologists. When accessing VSI HoloMedicine from a wireless head-mounted display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use
Council Directive	93/42/EEC
Classification incl. rule acc. Annex IX	Class I Active, noninvasive medical device of class I according rule 1 and 12 See Annex below
Conformity Assessment Procedure acc. Annex X	Technical documentation available upon request
Standards	See Annex below

The VSI HoloMedicine is manufactured in accordance with the standards and regulation mentioned in Annex A.

apoQlar GmbH declares that the mentioned products do not incorporate as an integral part:

- A substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of the Council Directive 93/42/EEC and which is liable to act upon the body with action ancillary to that of the device;
- A human blood derivative as defined in Article 1 of the Council Directive 93/42/EEC of the European Parliament and of the Council;
- Tissues of animal origin referred to in Regulation 93/42/EEC;
- Phthalates within the meaning of a provision of Council Directive 93/42/EEC as amended;
- PFOS (perfluoroctansulfonates) within the meaning of a provision of Council Directive No. 2006/122/EC as amended.

The technical documentation is available upon request.

The declaration is valid through the date of signature below.

25/9/2023 — Date

DocuSigned by: 12E05B595FE3471...

Liliana Duarte, Chief Product Officer (CPO)

25/09/2023 — Date

DocuSigned by: 4BDD656481AF47B...

Seyma Inceli, Head of Regulatory Affairs and QMS

Annex A- Applied Standards and Regulation

Standards	Title
EN ISO 13485:2016/A11:2021	Medical devices - Quality Management Systems-Requirements for regulatory purposes
EN ISO 14971:2019/A11:2021	Medical devices- Application of risk Management to medical devices
EN 62304:2006+A1:2015	Medical device software – Software life cycle processes
ISO/TR 20416:2020	Medical devices - Post market surveillance for manufacturers

21 CFR 820	Quality System Regulation
Council Directive 93/42/EEC	Medical Devices Directive (MDD)

Annex B – Device Classification

The VSI Holomedicine® is according to directive 93/42/ECC Annex IX a **non-invasive medical device**, as no part of the system is in contact with the patient. As the operation of the system requires electrical energy, the system is an **active medical device**. It is as well a complementary **diagnostic device**, as it is intended to provide – in combination with other medical devices - information for the identification of the anatomical structure of the patient. As the system will be applied on a specific patient less than an hour, it is described as for **transient use**.

The VSI Holomedicine® is a supporting system for medical viewing in 3D to help clinicians to see anatomical structures. It is not intended for diagnostic purposes.

For the classification of VSI Holomedicine® according to directive 93/42/ECC Annex IX are the rules for non-invasive products (rule 1-4), the additional rules for active products (rule 9-12) as well as specific rules (rule 13-18) relevant. The rules for invasive products (rule 5-8) are not applicable:

- According to rules 2-4 no specific critical function as described in this rules apply. Hence the system is of class I according to this rules.
- Rules 5-8 do not apply, as the product is non-invasive
- Rule 9 does not apply, as the product is not and does not directly control an active therapeutic device
- Rule 10 does not apply, as the product does not transfer energy to the patient, does not image in vivo distributions of radiopharmaceuticals and does not control vital body-functions.
- Rule 11 does not apply, as the product is not intended to administer and/or remove substances to or from the body of the patient.
- Hence, Rule 12 apply and the product is classified as class I according to rule 12
- The special rules 13-18 do not apply.

Summary

According to Annex IX of directive 93/42/ECC the VSI Holomedicine® is classified as **Class I** product. Hence, to provide the CE marking of the device, the conformity procedure according to directive 93/42/ECC Annex VII applies and a respective declaration of conformity has to be available upon request.

Revision	Date	Summary of change	Authorized by	
A	12/02/2021	Initial issue	CEO	
B	26/11/2021	Standard update - BS EN ISO 13485:2016+A11:2021	CEO	
C	3/12/2021	Annex A was updated Regulation was corrected – VSI HoloMedicine® is compliant with 93/42/ECC RA Specialist's and CRAO's signatures were added	RA Specialist	CRAO
D	02/2/2022	The intended use and version number were updated.	COO	Regulatory Affairs Manager

E	25/7/2022	The intended use and version number were updated.	COO	Regulatory Affairs Manager
F	25/09/2023	Software version number was updated.	CPO DocuSigned by: 12E05B595FE3471...	Head of Regulatory Affairs and QMS DocuSigned by: Seyma Inceli 4BDD656481AF47B...