EU Declaration of Conformity

ViroCAP derma

RUCK ViroCap Kaltplasma

Manufacturer:

Viromed Medical AG
Hauptstraße 105
25462 Rellingen
Germany
SRN: DE-MF-000047406

Authorized representative (if applicable)

Not applicable.

Viromed Medical AG hereby declares conformity in accordance with Article 52(7) of Regulation (EU) 2017/745, based on the technical documentation set out in Annexes II and III. This EU Declaration of Conformity is drawn up in accordance with Article 19 and Annex IV.

The **ViroCAP derma** and its accessories are also subject to the following Union legislation, where applicable:

a) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS). Conformity is supported by the technical documentation prepared in accordance with EN IEC 63000:2018 and by supplier declarations/material compliance evidence retained in the technical documentation.

b) Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries. Conformity is supported by the declaration of conformity and technical documentation of the incorporated replaceable battery, including applicable safety, labelling and substance-restriction information retained in the technical documentation.The quality management system is certified according to EN ISO 13485:2016 under certificate no. MD824231 issued by BSI Group The Netherlands B.V.

RUCK ViroCap Kaltplasma is included as a customer-specific trade name, labeling and configuration variant of ViroCAP derma. The regulatory manufacturer remains Viromed Medical AG. The intended purpose, indications, intended users, patient population and performance claim remain unchanged.

This EU declaration of conformity is issued under the sole responsibility of Viromed Medical AG.

This declaration of conformity remains valid until a new declaration of conformity is issued due to a change of the medical device.

Common Specifications applied: Not applicable.

Signed for and on behalf of Viromed Medical AG:

Rellingen, 03.07.2026

Uwe Perbandt, Chairman of the Executive Board

Name and identification of the device covered by this declaration of conformity		
Variant / Configuration	ViroCAP derma: standard configuration	RUCK ViroCap Kaltplasma: customer-specific trade name, labeling and configuration variant
Device Name, product or trade name	ViroCAP derma	RUCK ViroCap Kaltplasma
Article Number	144	1310001
UDI-DI	4262518941442	4262518942449
Basic UDI-DI	426251894-ViroCAPderma-G2	426251894-ViroCAPRUCK-Y3
Intended Purpose	The plasma device in combination with the appropriate spacer is an active non-therapeutic medical device for the reduction of bacteria or fungi in dermatological skin diseases with cold atmospheric plasma by medical professionals.	
Risk Class	Medical device class I according to Annex VIII of Regulation (EU) 2017/745.	
Accessories		
Name	Spacer, non-sterile, PU 12 / Spacer, non-sterile, single	Disposable Spacer for RUCK ViroCap Cold Plasma, turquoise, non-sterile, 12 pieces / Disposable Spacer for RUCK ViroCap Cold Plasma, turquoise, non-sterile, 1 piece
Article Number	151 / 152	1310101
Basic UDI-DI	426251894-Spacerderma-KU	426251894-Spacer-RUCKPP

Revision History

Version	Author/Revised by	Date	Description of Change
1.0	Christoph v. Ziegner	24.11.2025	Initial Version
2.0	Christoph v. Ziegner	19.05.2026	- Addition of title “ViroCAP” - Addition of spacer as accessory - Change of Applicable Annex - revised wording for greater accuracy - Addition of validity
3.0	Christoph v. Ziegner	03.07.2026	Addition of RUCK ViroCap Kaltplasma as a customer-specific trade name, labeling and configuration variant; addition of article number, UDI-DI and Basic UDI-DI according to EUDAMED / technical documentation.