

Certificate

Of Marketing Authorization of Medical Product

within Germany, the member states of the European Union
and the other states having a contractual agreement with the European Economic Area

Nr. **00128381**

Issued on the basis of the Declaration of conformity and registration taking into account Article 11 of Regulation (EU) 2017/745 (MDR) on Medical Devices and Medical Device Implementing Act (MPDG)

Ausgestellt auf Grund der Konformitätserklärung und Registrierung unter Berücksichtigung der Verordnung (EU) 2017/745(MDR) Artikel 11 über Medizinprodukte und Medizinprodukte-recht-Durchführungsgesetz (MPDG)

Manufacturer / Hersteller

Research and Production Company "VINAR", LLC

Gospitalnyi Val, 5 bldg. 7A office VIII
Moscow, 105094 RUSSIA
Phones/Fax: +7 495 988 7667
e-mail: vinar@vinar.ru, www.vinar.ru

Product name / Produkt

SteriT[®] Sterilization packaging materials

1. SteriT[®] Heat-seal, self-seal paper pouches
2. SteriT[®] Heat-seal, self-seal paper/plastic pouches
3. SteriT[®] Paper/plastic reels
4. SteriT[®] Heat-seal, self-seal Tyvek/plastic pouches
5. SteriT[®] Tyvek/plastic reels
6. SteriT[®] Polyamide reels
7. SteriT[®] Heat-seal, self-seal Paper/PET pouches
8. SteriT[®] Packaging material for sterilization of medical devices

Registration number / Registriernummer

DE/CA59/1587/76MDR

Classification / Klassifizierung

Class I

Nomenclature code / Nomenklaturcode

13 - 735

Nomenclature term/Nomenklaturbezeichnung

**Sterilization Packaging/
STERILGUTVERPACKUNGSSYSTEM**

Registration date : **2021-06-16**
Registrierdatum

Valid to : **2026-05-31**
Gültig bis

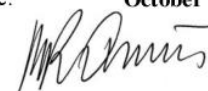
First Registration : **2015-05-04**
Erstregistrierung

Represented in the EC by:

Polmed.de Beata Rozwadowska
Fichtenstr. 12A, 90763 Fürth, Germany
email: info@polmed.de
Tel: +49 911 93163967



Date: **October 06, 2021**



Polmed.de

Certificate

Of Marketing Authorization of Medical Product

within Germany, the member states of the European Union
and the other states having a contractual agreement with the European Economic Area

Nr. **00128383**

Issued on the basis of the Declaration of conformity and registration taking into account Article 11 of Regulation (EU) 2017/745 (MDR) on Medical Devices and Medical Device Implementing Act (MPDG)

Ausgestellt auf Grund der Konformitätserklärung und Registrierung unter Berücksichtigung
der Verordnung (EU) 2017/745(MDR) Artikel 11 über Medizinprodukte und Medizinprodukte-recht-Durchführungsgesetz (MPDG)

Manufacturer / Hersteller

Research and Production Company "VINAR", LLC

Gospitalnyi Val, 5 bldg. 7A office VIII
Moscow, 105094 RUSSIA
Phones/Fax: +7 495 988 7667
e-mail: vinar@vinar.ru, www.vinar.ru

Product name / Produkt

SteriT[®] Adhesive tape for sterilization

SteriT[®] Adhesive indicator tape for steam sterilization
SteriT[®] Adhesive indicator tape for gas (EO) sterilization
SteriT[®] Adhesive indicator tape for gas (steam-formaldehyde) sterilization
SteriT[®] Adhesive indicator tape for radiation sterilization
SteriT[®] Adhesive indicator tape for vapor hydrogen peroxide sterilization
SteriT[®] Adhesive indicator tape for dry heat sterilization
SteriT[®] Adhesive tape for steam, ethylene oxide, steam-formaldehyde, radiation sterilization without indicator

Registration number / Registriernummer

DE/CA59/1587/77MDR

Classification / Klassifizierung

Class I

Nomenclature code / Nomenklaturcode

13 - 731

Nomenclature term/Nomenklaturbezeichnung

**Sterilization Packaging/
STERILGUTVERPACKUNGSSYSTEM**

Registration date : **2021-06-16**
Registrierdatum

Valid to : **2026-05-31**
Gültig bis

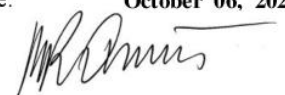
First Registration : **2015-05-04**
Erstregistrierung

Represented in the EC by:

Polmed.de Beata Rozwadowska
Fichtenstr. 12A, 90763 Fürth, Germany
email: info@polmed.de
Tel: +49 911 93163967



Date: **October 06, 2021**



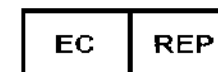
Polmed.de

Annex 1: List of devices produced by « VINAR », LLC
 registered in German (BfArM – DMIDS) with CE marking

Research and Production Company "VINAR", LLC
 Gospitalnyi Val, 5 bldg. 7A office VIII
 Moscow, Russia, 105094
 Phones/Fax: +7 495 988 7667
 e-mail: vinar@vinar.ru
 www: www.vinar.ru



	Name English	Nomenclature term English / German	UMDNS Code	Class	Form number DMIDS	Registration number DMIDS	Certificate number (No.document) DMIDS	Registration date DMIDS	Exp. date
1.	SteriT® Sterilization packaging materials 1. SteriT® Heat-seal, self-seal paper pouches 2. SteriT® Heat-seal, self-seal paper/plastic pouches 3. SteriT® Paper/plastic reels 4. SteriT® Heat-seal, self-seal Tyvek/plastic pouches 5. SteriT® Tyvek/plastic reels 6. SteriT® Polyamide reels 7. SteriT® Heat-seal, self-seal Paper/PET pouches 8. SteriT® Packaging material for sterilization of medical devices	Sterilization Packaging / STERILGUTVERPACKUNGS- SYSTEM	13-735	I	00197907 changed by 00338212 changed by 00313369	DE/CA37/1587/76E changed by DE/CA37/1587/76MDR changed by DE/CA59/1587/76MDR	00128381	2015-05-04 changed by 2021-06-16	2026-05-31
2.	SteriT® Adhesive tape for sterilization 1. SteriT® Adhesive indicator tape for steam sterilization 2. SteriT® Adhesive indicator tape for gas (EO) sterilization 3. SteriT® Adhesive indicator tape for gas (steam-formaldehyde) sterilization 4. SteriT® Adhesive indicator tape for radiation sterilization 5. SteriT® Adhesive indicator tape for vapor hydrogen peroxide sterilization 6. SteriT® Adhesive indicator tape for dry heat sterilization 7. SteriT® Adhesive tape for steam, ethylene oxide, steam-formaldehyde, radiation sterilization without indicator	Sterilization Process Indicators / STERILISATIONSPROZESS- INDIKATOR	13-731	I	00197909 changed by 00338206 changed by 00313369	DE/CA37/1587/77E changed by DE/CA37/1587/77MDR changed by DE/CA59/1587/77MDR	00128383	2015-05-04 changed by 2021-06-16	



Polmed.de, Beata Rozwadowska
 Fichtenstr. 12A, 90763 Fürth
 Germany email: info@polmed.de