ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 17 07 53618 024

Manufacturer:

ZHERMACK S.p.A
Via Bovazecchino, 100
45021 Badia Polesine (RO)
ITALY

Facility(ies):

ZHERMACK S.p.A
Via Bovazecchino, 100, 45021 Badia Polesine (RO), ITALY

Product Category(ies):

Disinfectants for medical devices

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: ITA949069

Valid from: 2017-10-18
Valid until: 2022-10-17

04052768133229

Date, 2017-08-03

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

Zertifiziervertrag

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

– Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:

– Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.

– Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.

On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuev-sued.de/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:

– Validity of the quoted test standard(s)

In addition for certificates with the right to use a certification mark and for QM certificates:

– Conditions for an adequate manufacturing are maintained

– Regular surveillance of the facility is performed

Akkreditierungen / Benennungen (Status 14.10.2013) /
Accreditations / notifications (as of 2013-10-14)

Deutschland / Germany

Produktsicherheitsgesetz (ProdSG) /
Product Safety Act (ProdSG)

Europa / Europe

- Niederspannungsrichtlinie 2006/95/EG
- Spielzeugrichtlinie 2009/48/EG
- Richtlinie für aktive medizinische Implantate 90/385/EWG
- Richtlinie für Medizinprodukte 93/42/EWG
- Richtlinie für In-vitro-Diagnostika 98/79/EG
- Richtlinie für Gasverbrauchseinrichtungen 2009/142/EG
- Richtlinie für persönliche Schutzausrüstungen 89/686/EWG
- EMV-Richtlinie 2004/108/EG
- Richtlinie für Sportboote 94/25/EG + 2003/44/EG
- Richtlinie für Maschinen 2006/42/EG
- Richtlinie für Ex-Schutz Geräte 94/9/EG

- Low Voltage Directive 2006/95/EC
- Toys Directive 2009/48/EC
- Directive for Active Implantable Medical Devices 90/385/EEC
- Directive for Medical Devices 93/42/EEC
- Directive on In Vitro Diagnostic Medical Devices 98/79/EC
- Directive for Gas Appliances 2009/142/EC
- Directive for Personal Protective Equipment 89/686/EEC
- EMC Directive 2004/108/EC
- Directive for Recreational Craft 94/25/EC + 2003/44/EC
- Directive for Machinery 2006/42/EC
- Directive for Ex Safe Equipment 94/9/EC

- ENEC Agreement for luminaires, household and IT equipment

USA

- Nationally Recognized Testing Laboratory (NRTL) to 29 CFR 1910.7 by OSHA
- Accredited for FDA 510(k) Third Party Review
- Conformity Assessment Body to the MRA for Medical Devices; FDA QSReg Inspections, FDA 510(k) Third Party Review

Asien-Pazifik Region / Asia Pacific

- Recognized Certification Body to Electrical Products (Safety) Regulation; Hong Kong
- Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Australien / Australia
- Konformitätsbewertungsstelle / Conformity Assessment Body to the MRA for Medical Devices; Neuseeland / New Zealand

Weltweit / Worldwide

- NCB im CB-Scheme des IECEE /
  NCB in the CB Scheme of IECEE
- ExCB im IECEx-Scheme des IECEE /
  ExCB in the IECEx Scheme of IECEE
- Zertifizierstellen durch DAkkS akkreditiert
  DE-ZE-11321-01, DE-ZM-11321-09 und DE-ZM-11321-01.
  Certification Bodies accredited by DAkkS
  DE-ZE-11321-01, DE-ZM-11321-09 and DE-ZM-11321-01.

Zertifizierstelle für Produkte / Certification Body for Products • e-mail ps-zert@tuev-sued.de
Zertifizierstelle für Medizinprodukte / Certification Body for Medical Devices • e-mail medical_devices@tuev-sued.de
Kundenservice / Clients Services • Phone +49/89/50 08-42 61 • Fax +49/89/50 08-42 30 • e-mail ps-zert@tuev-sued.de

Zhermack

DECLARATION OF CONFORMITY

Manufacturer:	ZHERMACK SPA VIA BOVAZECCHINO, 100 45021 BADIA POLESINE (RO) ITALY		
Product:	**ITEM CODE**	**NAME**	**PACKAGING**
	C810001	Zeta 1 Ultra	1 bottle 5000 ml
	C810000	Zeta 1 Ultra	1 bottle 1000 ml
	C810002	Zeta 1 Ultra	1 bottle 125 ml
	C810011	Zeta 2 Sporex	1 jar 900 g
	C810012	Zeta 2 Enzyme	1 jar 1200 g
	C810021	Zeta 3 Ultra	1 bottle 750 ml
	C810023	Zeta 3 Soft	1 bottle 750 ml
	C810024	Zeta 3 Soft	2 bottles 2500 ml
	C810029	Zeta 3 Soft	1 bottle 125 ml
	C810027	Zeta 3 Soft	1 bottle 750 ml
	C810028	Zeta 3 Soft	2 bottles 2500 ml
	C810032	Zeta 3 Soft	1 bottle 125 ml
	C810025	Zeta 3 Foam	1 bottle 750 ml
	C810026	Zeta 3 Foam	1 bottle 3000 ml
	C810062	Zeta 3 Wipes Total	1 bag 120 wipes
	C810063	Zeta 3 Wipes Total	1 tub 120 wipes
	C810064	Zeta 3 Wipes Pop-up	1 bag 100 wipes
	C800061	Zeta 5 Unit	1 bottle 5000 ml
	C810048	Zeta 7 Solution	1 bottle 1000 ml
	C810052	Zeta 7 Solution	1 bottle 125 ml
	C810050	Zeta 7 Spray	1 bottle 750 ml
	C810053	Zeta 7 Spray	1 bottle 125 ml
	C810040	Zeta 5 Power Act	1 bottle 1000 ml
	C810038	Zeta 5 Power Act	1 box 50 unit dose (10 ml)
Classification:	CLASS IIa: Zeta 3 Wipes Pop-up, Zeta 5 Unit, Zeta 7 Solution, Zeta 7 Spray, Zeta 5 Power Act. CLASS IIb: Zeta 1 Ultra, Zeta 2 Sporex, Zeta 2 Enzyme, Zeta 3 Ultra, Zeta 3 Soft, Zeta 3 Foam, Zeta 3 Wipes Total. RULE 15 ANNEX IX OF THE MDD 93/42/CEE amended by 2007/47/CE		
Intended Use :	Disinfectants for Medical Device		

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/CEE AMENDED BY 2007/47/CE FOR MEDICAL DEVICES, IN ACCORDANCE WITH THE ANNEXES I, (II (excluding 4) and/or V and/or VII based on the classification), X, XII. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

Harmonized Standards applied:	UNI EN ISO 13485 :2012 UNI CEI EN ISO 14971 :2012 UNI EN 1041:2013 UNI EN 980:2009
Technical standards ref.:	Zeta 1 Ultra: EN 13727:2012, EN 14561:2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013, EN 14562:2006 (C. albicans, A.niger), EN 14348:2005, EN 14563:2008 (M. terrae, M. avium), EN 14476:2013 (Poliovirus, Adenovirus).

REVISION	DATE	DESCRIPTION
22	01/04/16	Reformulation of Intended Use in alignment with products labeling
23	01/02/17	Addition of codes C810038/ C810040 Zeta 5 Power Act and related data. Removal of the withdrawn code C810030.General review.
24	15/03/17	Correction of typing error in packaging description of code C810011 (90 g instead of 900 g).
25	18/10/2017	Obtaining renewed certificate that replaces the old ones (G2 15 05 53618 021)

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C.F. e P.IVA IT00594630295
R.E.A. 86603 - R.I. RO 00594630295
M. RO 001381 - Isc. Reg. A.E.E. IT07111000002
Cap. Soc. € 1.032.000,00

	Zeta 3 Ultra: EN 13727:2012, EN 14561:2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013, EN 14562:2006 (C. albicans, A. niger), EN 14348:2005, EN 14563:2008 (M. terrae, M. avium), EN 14476:2013 (Poliovirus, Adenovirus). Zeta 3 Soft: EN 13727:2012, EN 14561:2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013, EN 14562:2006 (C. albicans), EN 14348:2005, EN 14563:2008 (M. terrae), EN 14476:2013 (Poliovirus, Adenovirus, Parvovirus). Zeta 3 Foam: EN 13727:2012, EN 14561 :2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013, EN 14562:2006 (C. albicans), EN 14348:2005, EN 14563:2008 (M. terrae), EN 14476:2013 (Poliovirus, Adenovirus, Parvovirus). Zeta 3 Wipes Total: EN 13727:2012, EN 14561:2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013, EN 14562:2006 (C. albicans), EN 14348:2005, EN 14563:2008 (M. terrae), EN 14476:2013 (Poliovirus, Adenovirus, Parvovirus). Reduction Factor efficacy of wipes (prEN 16615:2013, 10 min contact time): R>4Log vs. S. aureus, E. hirae, R>3Log vs. C. albicans, P. aeruginosa. Zeta 3 Wipes Pop-up: EN 14476:2013 (HBV, HCV, Adenovirus, Coronavirus, Norovirus, VRS, Polyomavirus, H1N1), EN 14476 (HSV), EN 14476 (Rotavirus); EN 13697, EN 1276, EN 14561, EN 14561 (MRSA); EN 13697 (A. niger), EN 14562 (A. fumigatus); EN 1650, EN 13624, EN 13697, EN 14562 (C. albicans); EN 14348, EN 14563 (M. terrae). Zeta 2 Sporex: EN 13727:2012, EN 14561:2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013, EN 14562:2006 (C. albicans, A. niger), EN 14348:2005, EN 14563:2008 (M. terrae, M. avium), EN 14476:2013 (Poliovirus, Adenovirus, Parvovirus), EN 13704:2002 (B. cereus). Zeta 2 Enzyme: EN 13727:2012, EN 14561:2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013, EN 14562:2006 (C. albicans), EN 14348:2005, EN 14563:2008 (M. terrae, M. avium), EN 14476:2013 (Poliovirus, Adenovirus, Parvovirus). Zeta 7 Solution: EN 13727:2012 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013 (C. albicans), EN 14348:2005, EN 14563:2008 (M. terrae), EN 14476:2013 (Poliovirus, Adenovirus, Parvovirus). Zeta 7 Spray: EN 13727:2012 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013 (C. albicans), EN 14348:2005, EN 14563:2008 (M. terrae), EN 14476:2013 (Poliovirus, Adenovirus, Parvovirus). Zeta 5 Power act (bottle/unit dose): EN 13727:2012, EN 14561:2006 (S. aureus, P. aeruginosa, E. hirae), EN 13624:2013, EN 14562:2006 (C. albicans), EN 14348:2005 (M. terrae), DVV/RKI:2014, DVV:2012,prEN 16777:2014 (all enveloped viruses, including the blood-borne viruses such as HIV, HBV and HCV, other enveloped viruses such as Herpex simplex virus and virus famiies such as orthomyxoviridae (including all human and animal influenza viruses like H5N1 and H1N1), filoviridae (ebola virus) and paramyxoviridae (measles virus).
EC certificate :	According to annex II excluding (4) of the Directive 93/42/EEC N° G1 15 04 53618 020 valid until 2020/05/05 TUV SUD PS (0123) Ridlerstrasse 65, 80339 Munchen – Germany Only for Zeta 3 Wipes Pop-up: According to annex V of the Directive 93/42/EEC N°G2 17 07 53618 024 valid until 2022/10/17 TUV SUD PS (0123) Ridlerstrasse 65, 80339 Munchen – Germany
Validity of Declaration of conformity:	Valid until 2020/05/05
Start of CE marking:	Lot number/Date of first CE marking: C810000 Zeta 1 Ultra 1000 ml: **74399** C810040 Zeta 5 Power act 1000 ml: **255429** C810038 Zeta 5 Power act 50 unit dose (10 ml): **255429** C810001 Zeta 1 Ultra 5000 ml: **74399** C810021 Zeta 3 Ultra 750 ml: **75574** C810023 Zeta 3 Soft 750 ml: **74398** C810024 Zeta 3 Soft 5000 ml: **74398** C810027 Zeta 3 Soft 750 ml: **91773** C810028 Zeta 3 Soft 5000 ml: **91773** C810025 Zeta 3 Foam 750 ml: **74768**

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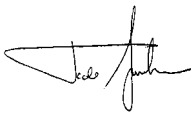
	C810026 Zeta 3 Foam 3000 ml: **74768** C810062 Zeta 3 Wipes Total Bag 120 pcs: **164717** C810063 Zeta 3 Wipes Total Tub 120 pcs: **164717** C810064 Zeta 3 Wipes Pop-up Bag 100 pcs: **3107461** C810011 Zeta 2 Sporex 900 g: **74408** C810012 Zeta 2 Enzyme 1200 g: **75707** C810048 Zeta 7 Solution 1000 ml: **75762** C810050 Zeta 7 Spray 750 ml: **75438** C800061 Zeta 5 Unit: **14/06/1998**

Badia Polesine, 18/10/2017

Paolo Ambrosini



General Manager
Zhermack S.p.A.

REVISION	DATE	DESCRIPTION
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Instructiuni pentru siguranta

1. Identificarea / prepararea substantei si prezentarea companiei

1.1 Identificarea substantei sau codul de preparare:

Cod:	C810061-C810060
Denumirea produsului	ZETA 3 SERVETELE

1.2 Utilizarea substantei /

Dezinfectant pentru suprafete si echipament dentar.

1.3 Prezentarea companiei

Nume	Zhermack S.p.a
Adresa completa	Via Bovazecchino
Localitate, tara	45021 Badia Polesine (RO) Italy Tel. +39 0425-597611 Fax +39 0425-53596

Adresa de e-mail a persoanei responsabile cu instructiunile de siguranta

tania.demetri@zhermack.com

1.4 Telefon de urgenta

Pentru intrebari urgente sunati la+39 0425-597611

2. Identificarea pericolului

2.1 Substanta/Clasificarea preparatului

F – Puternic imflamabil

Incadrari de risc

11 – Puternic imflamabil

Informatii legate de pericolele speciale pentru oameni si mediul inconjurator

Inhalarea cauzeaza efecte narcotice.

3. Compozitie / Informatii despre ingrediente

Caracterizare chimica

Servetele imbibate cu dezinfectant cu alcool

Ingrediente periculoase

CAS-No EC-No. Denumirea clasificarii [%]

64-17-5 200-578-6 Etanol < 45 F, R 11

4. Masuri de prin ajutor

(pentru informatii suplimentare cititi capitolul 16: Alte informatii)

Sfaturi generale

Nu sunt necesare masuri speciale.

In cazul inhalatiei

Scoateti persoana afectata la aer. Daca simptomele persista, chemati un doctor.

In cazul contactului cu pielea

Nu sunt necesare masuri speciale.

In cazul contactului cu ochii

Spalati imediat cu multa apa, deasemeni sub pleoape. Daca simptomele persista, chemati un doctor.

In caz de ingerare

Clatiti gura cu apa. Nu induceti voma. Cereti sfatul medicului si aratati-i ambalajul sau eticheta.

5. Masuri contra incendiilor

(pentru informatii suplimentare cititi capitolul 16: Alte informatii)

Medii corespunzatoare de stingere a focului

Spuma rezistenta la alcool, dioxid de carbon (CO_2), medii de stingere uscata, jet de apa

Medii de stingere a focului ce nu trebuiesc folosite din masuri de siguranta

Volum mare de apa

Masuri speciale pentru expunerea la pericol, luate din cauza substantei sau preparatului, produselor de combustie, gazelor rezultate

In caz de foc pot fie liberate:

Dioxid sau monoxid de carbon

Gaze iritante/corozive, inflamabile si toxice

Echipament special de protectie pentru stingerea focului

In caz de foc purtati costume prevazute cu sistem de respiratie

Alte informatii

Recipientele reci supuse riscului, vor fi stropite cu apa

Vaporii sunt mai grei decat aerul si pot forma amestecuri explosive cu aerul, chiar si in recipienti goi, care nu au fost curatati

6. Masuri contra accidentelor

(pentru informatii suplimentare cititi capitolul 16: Alte informatii)

Precautii personale

Asigurati o ventilatie adecvata. In cazul formarii de vapori (concentratie ridicata) utilizati masca de gaze.
Evitati contactul cu pielea, ochii si imbracamintea.

Precautii pentru mediul inconjurator

Nu aruncati in apele de suprafata sau in sistemul de scurgere.

Metode de curatare

Folositi un material absorbant (ex: nisip, silica gel, etc)
Aruncati materialul absorbant imbibat in containere corespunzatoare

7. Manipulare si depozitare

(pentru informatii suplimentare cititi capitolul 16: Alte informatii)

Manipularea

Sfaturi pentru manipularea in siguranta

Evitati contactul cu ochii.
Asigurati o aerisire adecvata, mai ales in incaperi inchise.

Masuri de precautie impotriva focului si exploziilor

Pastrati recipientul departe de foc, surse de aprindere sau suprafete incinse – nu fumati

Depozitarea

Cerinte pentru camerele si vasele de depozitare

Pastrati containerele bine inchise intr-un loc uscat si bine aerisit. Protejati impotriva razelor solare directe.

Asamblul de depozitare

Incompatibil cu agentii oxidanti.

Alte informatii legate de conditiile de depozitare

Tineti departe de mancare, bauturi sau mancarea animalelor.

8. Controlul expunerii / protectia personala.

8.1 Valorile limita ale expunerii

	Tip	Tara	TWA/8h		STEL/15 min		
			mg/m3	ppm	mg/m3	ppm	
PROPAN-2-OLO							
	TLV-ACGIH		491		982		Piele
	OEL	IRL		400		500	Piele
	WEL	UK		400		500	Piele

TLV al amestecului solventului: 491 mg/m3

8.2 Controlul expunerii

Pentru a minimaliza expunerea pe cat de mult posibil, se recomanda masuri adecvate, individuale de protectie: masca, ochelari, manusi. Nu mancati, nu beti si nu fumati atunci cand lucrati cu acest produs; spalati-va pe maini cu sapun si apa inainte de masa si dupa servici; se recomanda un dus.

9. Proprietati fizice si chimice

Aspect

Statut fizic: culoare, miros

Solid, servetele albe cu alcool

Date legate de siguranta (a solutiei)

Valori unitare

Punct de fierbere 85˚ C
Punct de topire < -10˚C
Punct de aprindere 25˚C
Inflamabil (Solid/faz) n.a. ˚C

Aspect

Statut fizic culoare, miros

Solid, servetele albe cu alcool
Temperatura de aprindere > 425˚C

Temperatura de autoaprindere n.a. ˚C

Gravitatie specifica (20˚C) aprox. 0.94 g/ml

Valorile minime de expunere 3.5 vol -%

Valorile maxime de expunere 19 vol -%

Solubilitatea in apa (20˚C)

pH – valoare 6-8

10. Stabilitate si reactivitate

(pentru informatii suplimentare cititi capitolul 16: Alte informatii)

Conditii de evitat

La caldura pot fi eliberati vapori inflamabili

Materiale ce trebuiesc evitate
Agenti oxidanti
Produse descompuse periculoase
Focul poate produce:
Dioxid si monoxid de carbon
Gaze iritante/corozive, inflamabile si toxice
Alte informatii
Nu vor aparea descompuneri daca modul de depozitare este corect

11. Informatii toxicologice

(pentru informatii suplimentare cititi capitolul 16: Alte informatii)
Efecte asupra oamenilor
Contactul cu ochii poate cauza iritatie
Poate provoca iritarea membranelor mucoase
Alte informatii
Inhalarea unei concentratii mari de vapori poate cauza efecte narcotice.
Daca este utilizat corespunzator si in conformitate cu regulile generale de igiena, nu este daunator.

12. Informatii legate de ecologie

(pentru informatii suplimentare cititi capitolul 16: Alte informatii)
Informatii generale
Nu aruncati produsul in apele de suprafata
Pericol minim pentru apa.

13. Aruncarea produsului

Codul/denumirea
07 06 99 fara specificatii
Produsul
Recomandare
Reciclarea este preferabila, atunci cand este posibila.
Poate fi incinerat conform legilor in vigoare.
Pachet contaminat
Recomandare
Containerele trebuiesc golite in mod optim, dupa o spalare adecvata poate fi dat la reciclare. Pachetele care nu pot fi curatate trebuiesc aruncate ca si produsul in sine.

14. Transportarea

Transportul (ADR/RID/GGVS/GGVE/ADNR)
Identificare 3175 SOLIDE CARE CONTIN LICHIDE INFLAMABILE, N.O.S. (contine etanol)
Clasa 4.1
UN-No 3175
Poluant marin no
PG II
EMS-No F-A, S-I
Remarci Cantitati limitate (capitolul 3.4): pachet combinat: 1.00 kg/30 kg (masa totala bruta)
Transport aerian ICAO/IATA
Denumirea corespunzatoare de transport SOLIDE CARE CONTIN LICHIDE IMFLAMABILE, N.O.S. (contine etanol)
Clasa 4.1
UN/ID No. 3175
PG II
Remarci PAC Y415: 0.5 kg/5

15. Reguli

Clasificare
In conformitate cu reglementarea CE privind substantele periculoase, acest produs trebuie marcat dupa cum urmeaza:
F Inflamabil puternic
R11 FOARTE IMFLAMABIL
S7 Pastrati containerul bine inchis
S16 Tineti departe de surse de aprindere – nu fumati

16. Alte informatii

Datele din paragrafele 4-8 si 10-12, partial nu se refera la utilizarea si domeniul de utilizare al produsului (in acest sens consultati informatiile referitoare la produs si la modul de utilizare).Aceste paragrafe se refera la masuri impotriva accidentelor si neregularitatilor.
(n.a. nu se aplica, n.d-nedeterminat)