Manufacturer acc. 93/42/ECC "MDD" Art. 1, 2. (f) and 2017/745 "MDR" Art. 1, 30:

curea medical GmbH
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Germany
SRN: DE/0000045282

Products:

- Basic-UDI 426022363-P-6S
  - curea P1
  - curea P1 DUO active
  - curea P2
- Basic-UDI 426022363-CC-TL
  - curea clean
  - curea clean breathe (BTBS)

The products described in this summary CER are a generic product group according 2017/745 Art. 1, 7.

Certificate Nos.:

- 44 232 117866
- 44 221 117866

Content

Introduction

The products evaluated with in this CER are medical devices according EU directive 93/42/ECC article 1 2. (f) and European Regulation 2017/745 article 1, 1.

For the clinical evaluation of the products mentioned above the literature route has been chosen, as there is sufficient published literature for equivalent devices available. The main products that has been chosen to compare to has been physically produced by our mother company McAirlaid's Vliesstoffe GmbH for a company called Sorbion AG between 2005 and 2010. Thus the construction, material composition and manufacturing processes are known in detail.

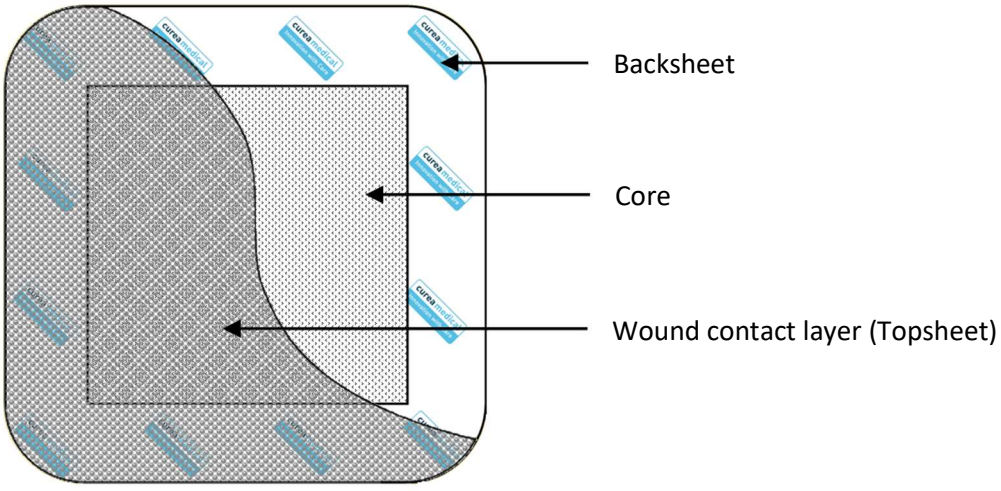
This CER does not claim to fully comply with MEDDEV 2.7/1 *Evaluation of clinical data,* as this is a summary evaluation only. The legal framework for this CER are

- European Directive 93/42/ECC, Annex IX
- European Regulation 2017/745 "MDR", Annex VIII

in the current version respectively.

Product description

All variants described within this summary CER consist of a superabsorbent core wrapped in an envelope made of polymer textiles or films.



Product variant	Wound Contact	Core	Backsheet
curea P1	Nonwoven (PP - CAS 9003-07-0)	C-525	BTBS: Laminate of PP + PE (CAS 9003-07-0 / CAS 9002-88-4)
curea P1 DUO active	Nonwoven (PP - CAS 9003-07-0)	C-525 + activated carbon	Nonwoven (PP - CAS 9003-07-0)
curea P2	Perforated PE film (CAS 9002-88-4)		Nonwoven (PP - CAS 9003-07-0)

curea clean	Nonwoven (PP - CAS 9003-07-0)	T-295	BTBS: Laminate of PP + PE (CAS 9003-07-0 / CAS 9002-88-4)
curea clean breathe (BTBS)	Nonwoven (PP - CAS 9003-07-0)	T-396	BTBS: Laminate of PP + PE (CAS 9003-07-0 / CAS 9002-88-4)

The absorbent cores consist of cellulose and cotton (CAS 65996-61-4) and sodium-polyacrylate (CAS 9003-04-7) in various ratios.

Biocompatibility

The materials for the products were chosen according their biocompatibility. All materials fulfil the requirements of EN ISO 10993 part 5 and part 10. The products itself were tested and or evaluated according the amended recommendations of EN ISO 10993-1 for

- Part 5 Cytotoxicity (test report no. 2020010634.1 dated 2020-01-31)
- Part 7 Gas residuals (test report no. 10057134.1 dated 2010-05-26)
- Part 10 Irritation and Sensitisation (test reports no. 2020010634.2 dated 2020-02-20 and test report no. 2020010634.3 dated 2020-03-30)
- Toxicology (expert report dated 2020-07-20)

Product functions

a) Absorption of watery fluids

Exsudate consists to > 90% of water. The sodium Polyacrylate is capable to absorb and physiko-chemically bind water in high ratios compared to its dry weight.
The products have been tested according EN 13726-1 and provide a specific absorption capacity of 1,59±0,09 g/cm² of core area (test reports no. SN 10331 vom 2010-07-29 und SN 11362-I vom 2011-01-12).

Compared to other “superabsorbent dressings” available on the EU market 2018 we found this benchmark:

Manufacturer	**Product**	**norm. absorption [g/cm²]**	**±SD**
Absorbest	Drymax Extra	1,49	0,04
Urgo	UrgoSupersuperabsorber	2,06	0,05
Urgo	UrgoSuperabsorber	1,53	0,03
Robin Wound	Eco Suuperabsorber	1,60	0,02
Fresenius Kabi	Tegaderm	1,46	0,03
Crawford	KerraMax Care	1,35	0,00

Klinion	Kliniderm	1,46	0,03
L+R	Vliwasorb	1,36	0,04
L+R	Vliwasorb Pro	1,27	0,05
Smith&Nephew	Duramax	1,41	0,13
BSN	SORBION sachet EXTRA	2,25	0,04
BSN	SORBION sachet S	2,30	0,08
Systagenix	Biosorb	2,07	0,03
B.Braun	Askina Absorb+	0,80	0,05
Coloplast	BIATAIN Super	0,66	0,02
IVF Hartmann	Zetuvit plus	1,48	0,02
Mölnlycke	Mextra	1,51	0,04

b) Binding of bacteria

Sodium polyacrylates are known to be able to bind gram-positive and gram-negative bacteria. We were able to prove this within a documented validation.

[15] Bruggisser R (2005): Bacterial and fungal absorption properties of a hydrogel dressing with a superabsorbent polymer core, J Wound Care 2005, Vol. 14 No. 9 pp. 438-442

Schmelz U (2011): Microbiological validation „curea P1“ – superabsorbent (resorbent) wound dressing, 2011-03-01

c) Binding of whole blood

The absorbent cores consisting of cellulose fibres and sodium polyacrylate granulate is capable to bind and retain whole blood.

Schmelz U (2012): Determination of the resorptive potential of the wound dressings “curea P1” and “curea P2” with respect to whole blood, plasma, serum and physiological saline, 2012-03-30

Comparative products

There are a lot of products available on the market that ware equal concerning technology, biology and clinical effectiveness (c.f. market benchmark above).

Literature

The literature listed below has been published for the products Sorbion Sachet and Sorbion Sana.

Literature	Evidence grade	Evaluation	Clinical outcome
[60] Sharp C (2010)	III Single case	informative	Exudate management also works with viscous coverings
[61] Butcher M (2010)	III Case series (n = 42)	informative	Review of 42 different patients:

	(Review)		Abdominal seam dissiscence, diabetic food syndrome, leg ulcer (venous and mixed), skin graft Clinical requirements were met fully
[62] Ribal E, et al. (2010)	IIb klin. Studie (n = 10)	informative	Exudate management on 10 patients with leg ulcer or pressure ulcers, retrospective comparison with hydrofibres or alginates
[63] Evans J (2010)	III Fallstudie	informative	Binding of MRSA
[64] Chadwick P (2009)	III Fallstudie	informative	multi-factorial foot ulcer
[65] Cutting KF (2009)	IIb clin. study (n = 53)	important	multicentric clinical study: 53 patients (abdominal seam dissiscence, diabetic foot syndrome, UCV, decubitus, vein donor site) Evidence of the reduction in the risk of maceration, 10% of the patient's wound closure after 4 weeks, 70% stable in the granulation phase
[66] Cutting KF, et al. (2007)	IIb clin. study (n = 26)	important	multicentric clinical study (12 UK centres)
[73] Beldon P (2008)	III Case series (n = 9)	important	Case series concerning PE in direct wound contact
[74] Beldon P (2009)	III Fallstudien (n = 10)	important	Case series on Sorbion Sana: 10 patients, NO sensitization caused by wound contact layer, evidence of atraumatic dressing changes
[70] Ousey K et al. (2013)	(Ia)	important	Literature review on 6 different superabsorbent dressings

The publications [60], [61], [63], [64], [65], [74], [75] and especially [70] - Ousey K et al. (2013) achieve the highest evidence ratings. A wide range of the most common types of wounds has shown that the wound dressings provide the desired clinical benefit. During the clinical application no adverse effect has been reported and no product-related drop out occurred.

[70] in particular summarizes the status of "superabsorbents" for six different manufacturers of superabsorbent dressings:

- Extended wear time (dressing change approx. Every 3 to 4 days)
- good exudate binding
- good exudate retention (prevention of maceration)
- Germ binding (in vitro and in vivo)
- MMP, elastase and radical binding (in vitro)

It is pointed out by the authors that they did not find any higher significance in the form of controlled, randomized studies either. The following criteria for the use of "superabsorbents" were identified:

- Do not use on dry or weakly exuding wounds
- Note the basic condition of the wound, including the infection status
- with delayed healing (= chronification)
- Dressing size must be appropriate to the size of the wound
- Duration of use, caution: weight of the wound pad in the course of absorption
- wound infection
- Under compression, swelling may lead to a local pressure increase
- Patient request
- Ease of use (flexibility and malleability)
- Cost efficiency

Summary and evaluation of clinical data

The own clinical data of the products considered here confirm the clinical benefits (exudate binding, germ binding, atraumatic dressing changes, blood binding) and the specific clinical safety. The data are not sufficient to make a statement about the general clinical safety of the products. But together with the published clinical data, there is sufficient evidence that the products of the “superabsorbent” type are well suited for exudate binding, maceration prevention and passive wound cleaning. Further biochemical effects are suspected and have been partially proven in vitro (germ binding). There is no clear clinical evidence of these effects (MMP inhibition, positive modification of the wound environment). The published clinical data are generally at a poor level of significance. Available “metananalyses” tend to summarize existing case series and should therefore be viewed as “literature reviews”.

Product-safety

Directive 93/42 / EEC requires in Appendix I:

a) ER1 - The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and

safety.

This shall include:

reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

=> With regard to usability, the products meet the expectations and the expected level of training of the users. The distinction between a watertight and a water-permeable side corresponds to the level of training and the state of the art. The instructions for use refer to the swelling of the wound dressings due to the absorption of exudate; the state of the art corresponds to a correspondingly elastic attachment of the dressing to the patient.

b) ER3 - The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.

=> Over their lifespan ("shelf life"), the products meet the absorption performance that is customary on the market and appropriate for the indication as well as the sterility is maintained.

c) ER6 - Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.

Neither in the literature nor in publicly accessible databases (e.g. BfArM) have any adverse effects on products of the same design been reported. The history of use has shown mild undesirable effects in the use of the products, but they have not caused any relevant physiological influence or even damage (reddening). The general biocompatibility of the products has been proven by appropriate testing.

History of safe use (dated 2019-12)

curea medical was founded in 2010 and started to market the wound dressings in 2010-07.

Year	Amount of marketed wound dressings [pieces]	Amount of complaints in total [cases]	Amount of application-related complaints [cases]	Identified product failures	no. of patients affected by product failure	SAE to be reported
Sum	**11.467.496**	**49**	**29**	**16**	**23**	**0**
2010	134.190	8	3	2	1	0
2011	540.555	3	1	1	0	0
2012	748.365	3	2	1	2	0
2013	918.110	8	6	4	5	0
2014	1.155.965	3	2	1	1	0
2015	1.358.630	3	2	1	1	0
2016	1.436.677	8	7	3	1	0
2017	1.449.533	5	4	2	2	0
2018	1.740.204	5	1	1	9	0

2019	1.985.267	3	1	0	1	0

The complaints relating to a person (only patients are affected) can be traced back to the following cases:

- Delamination of bonded wound dressings: Sodium polyacrylate is released into the wound. This problem was eliminated by changing the joining technology to ultrasonic welding. This error led to the accumulation of patient-related complaints in 2013 and continued to have an effect until 2016.
- Reddening of the skin under the wound pad (usually reported as "*contact allergy*"): Reddening of the skin in the area of chronic wounds is quite common and can also be attributed to various physiological reactions (e.g. thermal insulation and mechanical stimulus-> increased blood flow).
- Maceration of the wound edge: this problem is attributed to **a** too long application period that does not correspond to the individual wound situation.

Clinical Performance

The results of the available, published clinical data show that the use of superabsorbent wound dressings significantly improves the wound environment:

- Increase in the rate of wound healing
- The released exudate is absorbed and maceration of the skin surrounding the wound is prevented or significantly reduced. The absorption also works **under** 46 mmHg of the compression therapy, but then with about 33% less capacity.
- Even infected wounds benefit from the ability of this type of wound dressing to bind bacteria (germs) and the fact that these bacteria are removed when the dressing is changed.
- In addition, the use of superabsorbent wound dressings seems to have a positive influence on the development of wound odor, which can be attributed to the reduction of the bacterial load in the wound.

Acceptance of the side effects

The accessible, published literature does not indicate any serious side effects or adverse events in the context of clinical application. "Drying out" of wounds through the use of superabsorbent wound dressings has not been reported by any study - not even with product comparisons.

The risk of serious (long-term or permanent) damage to the patient's health is reduced to a few cases:

- Loss of tendons, bones and other hyaline tissues (covered by the contraindications in the instructions for use)
- Anaphylactic shock due to the ingredients is by the successful examination acc. EN ISO 10993-5 and -10 secured and a toxicological report **ensured**
- Blood loss through bleeding into the wound dressing (this would require an untreated, bleeding wound and therefore **does** not meet the standard of therapy)

- Generation of tension bubbles with adhesive wound dressings (is addressed in the instructions for use of the corresponding products and is a training point in the further training of wound therapists. Tension bubbles are an inherent risk of adhesive fastening of wound dressings to the human body in general.)

Physical damage to the user is as good as impossible when using the products and observing the general hygiene rules.

Summary and Conclusion

The inclusion of the published clinical data of the products that Sorbion placed on the market up to 2011 enables proof of the clinical benefit due to the extensive similarity of the products "Sorbion Sachet S" and "curea P1". The basic requirements o**f Directive 93/42/**EEC ER1, ER3 and ER6 are thus adequately documented.

Even the weak data situation for the product curea P1 clearly shows the clinical benefit by promoting the healing rate compared to the natural proliferation of an untreated wound. Overall, the additional advantages lead to an increase in the cure rate and also safeguard further risks for the patient, but also for the user (e.g. contamination / infection lock by the BTBS). The identified risks are recorded in the risk management system and **ensured** by suitable measures. Compared to failure to take care of the wound, the risks to be expected are completely justifiable.

This is confirmed by the complaint rate (user feedback) and the history of **safe use**.

Even in comparison with la**rgely similar products,** there are no indications of **unbearable** disadvantages. The materials used correspond to the state of medical technology. The evaluation of the available clinical data of the products available on the market did not reveal any evidence of undetected risks. Even an extension of the comparison to less related wound care products did not reveal any signs of systemic disadvantages.

Heilbad Heiligenstadt, 2020-09-09

C. Schulte, CTO

D. Bodmann, CEO

Unpublished expert reports on file:

- Haselbach J. et al. (2020): Legal Compliance and Biological/Toxicological Safety Evaluation of Wound Dressings “Curea P1” and Curea P2”, 2020-07-20
- Schmelz U (2011): Microbiological validation „curea P1“ – superabsorbent (resorbent) wound dressing, 2011-03-01
- Schmelz U (2012): Determination of the resorptive potential of the wound dressings “curea P1” and “curea P2” with respect to whole blood, plasma, serum and physiological saline, 2012-03-30

Unpublished test reports on file

- Absorption acc. EN 13726-1 test reports no. SN 10331 dated 2010-07-29 and SN 11362-I dated2011-01-12
- Cytotoxicity (test report no. 2020010634.1 dated 2020-01-31)
- Gas residuals (test report no. 10057134.1 dated 2010-05-26)
- Irritation (test reports no. 2020010634.2 dated 2020-02-20)
- Sensitization (test report no. 2020010634.3 dated 2020-03-30)

Published literature (excerpt)

[15] Bruggisser R (2005): Bacterial and fungal absorption properties of a hydrogel dressing with a superabsorbent polymer core, J Wound Care 2005, Vol. 14 No. 9 pp. 438-442

[17] Eming S, et al. (2008): The inhibition of matrixmetallo-proteinase activity in chronic wounds by a polyacrylate superabsorber, Biomaterials 29 (2008) pp 2932-2940

[60] Sharp C (2010): Managing the wound with Hydration Response Technology, Wounds UK 2010, Vol 6, No 2

[61] Butcher M (2010): Sorbion Sachet S: clinical application and results, J Wound Care supp. 05/2010, pp. 14-18

[62] Ribal E, et al. (2010): Performance of a Hydration Response Technology dressing in managing heavily exuding wounds, EWMA 2010, Poster

[63] Evans J (2010): Hydration Response Technology and managing infection, J Community Nursing, January 2010, Vol 24 Issue 1

[64] Chadwick P (2008): The use of sorbion sachet S in the treatment of a highly exuding diabetic foot wound, Diab Foot J, Vol 11, No 4 2008

[65] Cutting KF (2009): Managing wound exudate using a super-absorbent polymer dressing: a 53-patient clinical evaluation, J Wound Care, Vol 18 No5, 2009

[66] Cutting KF, et al. (2007): Clinical Evaluation of a new high absorbency dressing (n=26), Wounds UK 2007, Poster

[70] Ousey K et al. (2013): Superabsorbent wound dressings: A literature review, WoundsUK, Vol 9, No 3, 2013

[73] Beldon P (2008): Efficacy of Sorbion Sana dressings in managing exudate while preventing skin sensitivity in venous leg ulcer patients, EWMA 2008, Poster

[74] Beldon P (2009): Contact sensitivities in Chronic Wounds and the Need for Hypoallergenic Dressings, Europ. Dermatology, March 2009, 76-78