TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland InterCert Kft.

hereby certifies that the company

SC Titus and Sons SRL

Calea Buziasului 43/A/P
300700 Timisoara,
Romania

has established and maintains a quality management system
for medical devices for the following scope:

Manufacturing and distribution of sterile wound dressings with ointment

Proof has been furnished that the requirements of

MSZ EN ISO 13485:2012

are fulfilled. The certification is subject to periodic surveillance.

Certificate Registration No.: **OX 69251581 0001**
Audit report No.: **28229831 002**
This certificate is valid: **from 2016-01-14 to 2019-01-13**

Digitally signed by Botnaru Andrei
Date: 2019.01.30 10:18:25 EET
Reason: MoldSign Signature
Location: Moldova

NAT
MIR TANÚSÍTÓ
(MSZ EN ISO 13485)
NAT-4-0105/2015

TÜV Rheinland InterCert Kft. TÜVRheinland Notified Body 1008

2016-01-14
Date of issue

MD Zoltán Ambrus
Certifier

TÜVRheinland®

Certificate

The Certification Body of
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hereby certifies that the company

SC Titus and Sons SRL

Calea Buziasului 43/A/P
300700 Timisoara,
Romania

has established and maintains a quality management system
for medical devices for the following scope:

Manufacturing and distribution of sterile wound dressings with ointment

Proof has been furnished that the requirements of

EN ISO 13485:2012+AC:2012

are fulfilled. The certification is subject to periodic surveillance.

Certificate Registration No.: **OY 69251582 0001**
Audit report No.: **28229831 002**
This certificate is valid: **from 2016-01-14 to 2019-01-13**

TÜV Rheinland InterCert Kft. TÜVRheinland® Notified Body 0410

2016-01-14
Date of issue

MD Zoltán Ambrus
Certifier

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V

Quality Assurance System Production

Medical Devices

Registration No.: OD 69251583 001

Report No.: 28229831 002

Manufacturer: SC Titus and Sons SRL
Calea Buziasului 43/A/P
300700 Timisoara,
Romania

Products:

GMDN code	REF Name
16453	Sterile impregnated compresses with ointment, tubes and applicators with ointment NewBIOTIdermal

The Notified Body audited the quality system and certifies that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned directive. For placing on the market of Class IIb and Class III devices covered by this certificate, an EC type-examination certificate according to Annex III is required.

Issue Date: 2016-01-14

Effective Date: 2016-01-14

Expiry Date: 2021-01-13

Notified Body

TÜV Rheinland InterCert Kft. TÜVRheinland® 5 Notified Body 1008

MD Zoltán Ambrus

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, http://www.tuv.com/hun/

Titus & Sons
Qui sanat sit

DECLARAȚIE DE CONFORMITATE Nr.1
DECLARATION OF CONFORMITY No.1

CE 1008

Producător: Titus&Sons S.r.l., Calea Buziasului nr 43 A - parter,Timișoara
Manufacturer: Titus&Sons S.r.l., 43 A – parter Calea Buziasului street, RO, Timisoara

Noi, Titus&Sons S.r.l., declarăm pe proprie răspundere că produsele urmatoare:
The undersigned, Titus&SonsS.r.l., hereby declare on our own responsibility that the products:

Nr. Crt. *No.*	**Denumire dispozitiv medical** *Name of Medical Device*	**Numar lot** *Batch No.*	**Termen de valabilitate** *Validity Term*	**Cantitate** *Quantity*	**Clasa dispozitivului medical** *Class of Medical Device*
1	NewBIOTIdermal® comprese impregnate sterile 10cmX10cm 10buc/cutie individuala	10x10NBTD001	2019/04	15103	IIa
2	NewBIOTIdermal® comprese impregnate sterile 10cmX20cm 5buc/cutie individuala	10x20NBTD001	2019/04	2553	IIa
3	NewBIOTIdermal® aplicator cu unguent steril 50ml 1buc/cutie individuala	50NBTD001	2019/04	101	IIa
4	NewBIOTIdermal® aplicator cu unguent steril 8ml 1buc/cutie individuala	8NBTD001	2019/04	101	IIa

Corespunde cu prevederile Directivei 93/42/EEC, Anexa I – Cerințe Esențiale si cu standardele armonizate relevante
Conforms with the provisions of Directive 93/42/EEC, Annex I – Essential Requirements and relevant harmonized standards.

Procedura de evaluare a conformitatii: Anexa V la Directiva 93/42/EEC referitoare la dispozitivele medicale, transpusa prin Hotararea nr. 54/29.01.2009 privind conditiile introducerii pe piata a dispozitivelor medicale.
***Conformity assessment procedure: Annex V** to Directive 93/42/EEC regarding medical devices, according to the Romanian legislation by the Government Decision no. 54/29.01.2009 on the requirements for the placing on the market of medical devices.*

Date de identificare a certificatului EC: Certificat de conformitate emis de TUV Rheinland Intercert Kft nr: OY 692515820001
***EC Certificate identification details** Certificate of Conformity issued by TUV Rheinland Intercert Kft nr: OY 692515820001*

Date de identificare ale organismului de certificare:
Nume si adresa:

TÜV Rheinland Intercert Kft
H-1132 Budapest, Váci út 48/A-B
http://www.tuv.com
Phone: +36 (1) 329 8060 ext: 521.
Fax: +36 (1) 288 8499

Semnatar autorizat
Authorized signatory

Nume si Prenume *(Name)*:
Mihaela Noditi
Functia: **Director Calitate**

Locul si data emiterii
Date and place of issuance

Timișoara, 20.04.2016

Titus & Sons

DECLARAȚIE DE CONFORMITATE Nr.2
DECLARATION OF CONFORMITY No.2

CE 1008

Producător: Titus&Sons S.r.l., Calea Buziasului nr 43 A - parter,Timișoara
***Manufacturer: Titus&Sons S.r.l.**, 43 A – parter Calea Buziasului street, RO, Timisoara*

Noi, Titus&Sons S.r.l., declarăm pe proprie răspundere că produsele urmatoare:
The undersigned, Titus&SonsS.r.l., hereby declare on our own responsibility that the products:

Nr. Crt. *No.*	**Denumire dispozitiv medical** *Name of Medical Device*	**Numar lot** *Batch No.*	**Termen de valabilitate** *Validity Term*	**Cantitate** *Quantity*	**Clasa dispozitivului medical** *Class of Medical Device*
1	NewBIOTIdermal® aplicator cu unguent steril 50ml 1buc/cutie individuala	50NBTD001	2019/04	2701	IIa
2	NewBIOTIdermal® aplicator cu unguent steril 8ml 1buc/cutie individuala	8NBTD001	2019/04	2701	IIa

Corespunde cu prevederile Directivei 93/42/EEC, Anexa I – Cerințe Esențiale si cu standardele armonizate relevante
Conforms with the provisions of Directive 93/42/EEC, Annex I – Essential Requirements and relevant harmonized standards.

Procedura de evaluare a conformitatii: Anexa V la Directiva 93/42/EEC referitoare la dispozitivele medicale, transpusa prin Hotararea nr. 54/29.01.2009 privind conditiile introducerii pe piata a dispozitivelor medicale.
***Conformity assessment procedure: Annex V** to Directive 93/42/EEC regarding medical devices, according to the Romanian legislation by the Government Decision no. 54/29.01.2009 on the requirements for the placing on the market of medical devices.*

Date de identificare a certificatului EC: Certificat de conformitate emis de TUV Rheinland Intercert Kft nr: OY 692515820001
***EC Certificate identification details** Certificate of Conformity issued by TUV Rheinland Intercert Kft nr: OY 692515820001*

Date de identificare ale organismului de certificare:
Nume si adresa:

TÜV Rheinland Intercert Kft
H-1132 Budapest, Váci út 48/A-B, http://www.tuv.com
Phone: +36 (1) 329 8060 ext: 521.
Fax: +36 (1) 288 8499

Semnatar autorizat
Authorized signatory

Nume si Prenume *(Name)*
Mihaela Noditi
Functia: **Director Calitate**
Title: ***Quality Director***

Locul si data emiterii
Date and place of issuance

Timișoara, 25.05.2016

Titus & Sons

DECLARAȚIE DE CONFORMITATE Nr.3
DECLARATION OF CONFORMITY No.3

CE 1008

Producător: Titus&Sons S.r.l., Calea Buziasului nr 43 A - parter,Timișoara
***Manufacturer: Titus&Sons S.r.l.**, 43 A – parter Calea Buziasului street, RO, Timisoara*

Noi, Titus&Sons S.r.l., declarăm pe proprie răspundere că produsele urmatoare:
The undersigned, Titus&SonsS.r.l., hereby declare on our own responsibility that the products:

Nr. Crt. *No.*	Denumire dispozitiv medical *Name of Medical Device*	Numar lot *Batch No.*	Termen de valabilitate *Validity Term*	Cantitate *Quantity*	Clasa dispozitivului medical *Class of Medical Device*
1	NewBIOTIdermal® comprese impregnate sterile 10cmX10cm 10buc/cutie individuala	10x10NBTD002	2019/09	30003	IIa
2	NewBIOTIdermal® Tub cu unguent steril 20ml 1 buc/cutie individuala	20NBTD001	2019/10	3204	IIa
3	NewBIOTIdermal® Tub cu unguent steril 40ml 1 buc/cutie individuala	40NBTD001	2019/10	3146	IIa
4	NewBIOTIdermal® Tub cu unguent steril 75ml 1 buc/cutie individuala	75NBTD001	2019/10	3115	IIa

Corespunde cu prevederile Directivei 93/42/EEC, Anexa I – Cerințe Esențiale si cu standardele armonizate relevante
Conforms with the provisions of Directive 93/42/EEC, Annex I – Essential Requirements and relevant harmonized standards

Procedura de evaluare a conformitatii: Anexa V la Directiva 93/42/EEC referitoare la dispozitivele medicale, transpusa prin Hotararea nr. 54/29.01.2009 privind conditiile introducerii pe piata a dispozitivelor medicale.
***Conformity assessment procedure: Annex V** to Directive 93/42/EEC regarding medical devices, according to the Romanian legislation by the Government Decision no. 54/29.01.2009 on the requirements for the placing on the market of medical devices.*

Date de identificare a certificatului EC: Certificat de conformitate emis de TUV Rheinland Intercert Kft
nr: OY 692515820001
***EC Certificate identification details** Certificate of Conformity issued by TUV Rheinland Intercert Kft*
nr: OY 692515820001

Date de identificare ale organismului de certificare:
Nume si adresa:

TÜV Rheinland Intercert Kft
H-1132 Budapest, Váci út 48/A-B
http://www.tuv.com
Phone: +36 (1) 329 8060 ext: 521.
Fax: +36 (1) 288 8499

Semnatar autorizat
Authorized signatory

Nume si Prenume *(Name)*:
Mihaela Noditi
Functia: **Director Calitate**
Title: ***Quality Director***

Locul si data emiterii
Date and place of issuance

Timișoara, 14.10.2016

Titus & Sons
Qui sanat sit

DECLARAȚIE DE CONFORMITATE Nr.4

DECLARATION OF CONFORMITY No.4

CE 1008

Producător: Titus&Sons S.r.l., Calea Buziasului nr 43 A - parter,Timișoara
***Manufacturer: Titus&Sons S.r.l.**, 43 A – parter Calea Buziasului street, RO, Timisoara*

Noi, Titus&Sons S.r.l., declarăm pe proprie răspundere că produsele urmatoare:
The undersigned, Titus&SonsS.r.l., hereby declare on our own responsibility that the products:

Nr. Crt. *No.*	**Denumire dispozitiv medical** *Name of Medical Device*	**Numar lot** *Batch No.*	**Termen de valabilitate** *Validity Term*	**Cantitate** *Quantity*	**Clasa dispozitivului medical** *Class of Medical Device*
1	NewBIOTIdermal® spray cu solutie unguent steril 75ml	75NBTD-S 001	2019/12	1836	IIa
2	NewBIOTIdermal® aplicator cu unguent steril 50ml 1buc/cutie individuala	50NBTD002	2019/12	1001	IIa

Corespunde cu prevederile Directivei 93/42/EEC, Anexa I – Cerințe Esențiale si cu standardele armonizate relevante
Conforms with the provisions of Directive 93/42/EEC, Annex I – Essential Requirements and relevant harmonized standards.

Procedura de evaluare a conformitatii: Anexa V la Directiva 93/42/EEC referitoare la dispozitivele medicale, transpusa prin Hotararea nr. 54/29.01.2009 privind conditiile introducerii pe piata a dispozitivelor medicale.
***Conformity assessment procedure: Annex V** to Directive 93/42/EEC regarding medical devices, according to the Romanian legislation by the Government Decision no. 54/29.01.2009 on the requirements for the placing on the market of medical devices.*

Date de identificare a certificatului EC: Certificat de conformitate emis de TUV Rheinland Intercert Kft nr: OY 692515820001
***EC Certificate identification details** Certificate of Conformity issued by TUV Rheinland Intercert Kft nr: OY 692515820001*

Date de identificare ale organismului de certificare:
Nume si adresa:

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H-1132 Budapest, Váci út 48/A-B, http://www.tuv.com
Phone: +36 (1) 329 8060 ext: 521.
Fax: +36 (1) 288 8499

Semnatar autorizat
Authorized signatory

Nume si Prenume *(Name)*:
Mihaela Noditi
Functia: **Director Calitate**
Title: ***Quality Director***

Locul si data emiterii
Date and place of issuance

Timișoara, 14.12.2016

Titus & Sons
Qui sanat sit

ISO 13485: 2012

Certificate of conformity

Product Name: QUASIDERM ®PROTECTOR hand cream
Analysis date: 20.11.2014 at **R& D CREAM LABORATORY**
Issue date: 03.07.2015
Test procedures was made according to: Ph.Eur.8/2014

CHARACTERISTICS	SPECIFICATIONS	RESULTS
Appearance	Homogenous cream	Homogenous cream
Colour	Yellowish	Yellowish
Odor	Pleasant, characteristic	Pleasant, characteristic
pH	5,5 – 7,5	6.75
Density, 25°C, g/cm^3	0,9000 – 1,0000	0.9600
Microscope (emulsion examination)	Fine, homogenous, uniform	Fine, homogenous, uniform
Stability (centrifuge, 3 cycles x 4000 rpm x 30')	No separation	No separation
Viscosity (25°C, Brookfiled, spindle 3, 10 rpm), mPa.s	40.000 – 60.000	48.000

Report of microbiological analysis - J.S.Hamilton SRL (attached)

Semnatar autorizat
Authorized signatory

Nume si Prenume *(Name)*: MIHAELA NOVITI
Functia: **Director Calitate**
Title: ***Quality Director***

Locul si data emiterii
Date and place of issuance

Timișoara, 17.12.2016