

CERTIFICATE OF ANALYSIS

HUMAN SKIN TISSUE AND DERIVATED PRODUCTS

Catalog number: TRA002

Batch number: TRA002791-OC07

FOR IN VITRO AND RESEARCH USES ONLY

For your safety /// Biohazard information /// These biologicals have to be considered as potentially dangerous, take maximum care in order to protect yourself, your colleagues and your environment.

According to French laws, this product is considered as “product and element of body taken during a surgical procedure”, and used for scientific research, French law L.1245 CSP.

1 BIOLOGICAL MATERIAL

INFORMATION		Comments		
<ul style="list-style-type: none"> • Sex • Origin • Anatomical site • Age • BMI 	<ul style="list-style-type: none"> • female <input checked="" type="checkbox"/> male <input type="checkbox"/> • Caucasian <input checked="" type="checkbox"/> African <input type="checkbox"/> Other <input type="checkbox"/> • abdomen <input checked="" type="checkbox"/> breast <input type="checkbox"/> face <input type="checkbox"/> other <input type="checkbox"/> • 53 years old • 30 			
SAFETY DATA				
Viological status	Specification	Result		
<ul style="list-style-type: none"> • Hepatitis B (<i>HBs antigen, anti HBc antibody</i>) • Hepatitis C (<i>anti HCV antibody</i>) • HIV-1 and HIV-2 (<i>anti HIV-1 and -2 antibodies</i>) 	Negative	Positive <input type="checkbox"/> Negative <input checked="" type="checkbox"/> In progress <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input checked="" type="checkbox"/> In progress <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input checked="" type="checkbox"/> In progress <input type="checkbox"/>		
<i>Viological status for HIV1-2, HCV, HBV is carried out on the patient by serological screening using approved diagnostic kits.</i>				
Biosafety level	All human sourced products should be handled at the Biological Safety Level. 2 (BSL 2) to minimize exposure of potentially infectious products			
DESCRIPTION				
Skin decontamination before surgery		Comments		
Betadine	<input type="checkbox"/>	Hibitane	<input type="checkbox"/>	
Betadine alcohol	<input checked="" type="checkbox"/>	Hibiscrub	<input type="checkbox"/>	
Betadine scrub	<input checked="" type="checkbox"/>	Chlorhexidine	<input type="checkbox"/>	
Chlorhexidine alcohol	<input type="checkbox"/>	Other	<input type="checkbox"/>	



8 -18 Rue Jean Pecker - 35000 Rennes, France
Tél. (33) 02 99 14 36 14 - Fax (33) 02 99 54 44 72

S.A.R.L. au capital de 98 500 €
R.C.S. Rennes B - SIRET 391 701 232 00012 - APE 332B - VAT n°FR 21 391 701 232

CERTIFICATE OF ANALYSIS

Shipping conditions between the sampling site and Biopredic		Comments
Time		
<ul style="list-style-type: none"> Transit time less than 6 h Transit time less than 12 h 	<input checked="" type="checkbox"/> <input type="checkbox"/>	Real time: 3h00
Temperature		
<ul style="list-style-type: none"> Room temperature Between +4°C and +15°C At less than -20°C 	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	

2 PRODUCT

Production information	
<ul style="list-style-type: none"> Surgery date Production date Production performed on 	May 10, 2012 at 00 h 24 PM May 11, 2012 at 9 h 00 AM fresh skin <input checked="" type="checkbox"/> frozen skin <input type="checkbox"/>
<ul style="list-style-type: none"> Full thickness skin with adipose tissue Full thickness skin without adipose tissue Dermatomed skin Stratum corneum 	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
Fresh <input type="checkbox"/>	Frozen <input checked="" type="checkbox"/>
Other <input type="checkbox"/> / <input type="checkbox"/>	
Surface	38 cm ²

3 CONTROL

Macroscopic examination of the full-thickness skin					
<ul style="list-style-type: none"> Presence of stretch marks Presence of scars Presence of marks (surgical marker) Presence of pubic hair 	Yes Yes Yes Yes	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	No No No No	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	
Control of dermatomed skin					
<i>Thickness of dermatomed skin measured with Palmer instrument (type BOUTILLON ref. TESA 074115651)</i>					
Criteria	Specification	Result			
<ul style="list-style-type: none"> Number of measures Mean of thickness Coefficient of variation (CV) 	300 μm < e < 700 μm CV ≤ 20%	4 e = 540 μm Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> CV = 3 %			

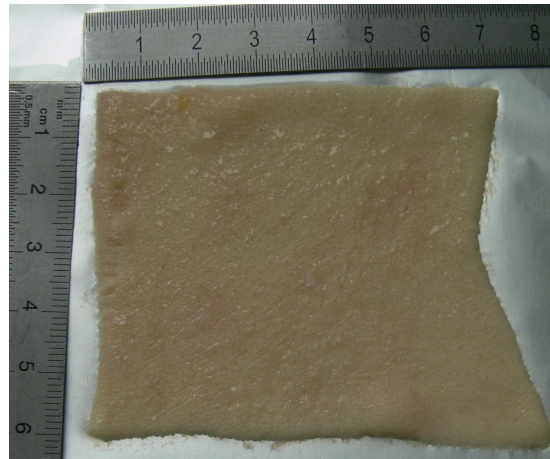


INTERNATIONAL
 8 - 18 Rue Jean Pecker - 35000 Rennes, France
 Tél. (33) 02 99 14 36 14 - Fax (33) 02 99 54 44 72

S.A.R.L. au capital de 98 500 €
 R.C.S. Rennes B - SIRET 391 701 232 00012 - APE 332B - VAT n°FR 21 391 701 232

CERTIFICATE OF ANALYSIS

Skin picture



4 STORAGE AND DELIVERY

Storage	
<ul style="list-style-type: none"> • At room temperature • At 4°C • At - 20°C • At - 80°C 	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
Delivery	
<ul style="list-style-type: none"> • At room temperature • At 4°C • At lower than - 20°C 	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>

VISA FOR BATCH RELEASE

Name	Signature	Date
Nathalie ROUGIER, PhD		May 14, 2012