

V3	COA PEA / EXP / TRA / STR	Created on July, 2010	Revised on June 10, 2011	To Revise on June, 2012
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fdl V3_0611 PEA020066-OC05

CERTIFICATE OF ANALYSIS

HUMAN SKIN TISSUE AND DERIVATED PRODUCTS

Catalog number: PEA020

Batch number: PEA020066-OC05

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 type="checkbox"/> breast <input type="checkbox"/> face <input checked="" type="checkbox"/> other <input type="checkbox"/> • 70 years old • 23 	
SAFETY DATA		
Virolological 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>Virolological 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"/> Betadine alcohol <input type="checkbox"/> Betadine scrub <input type="checkbox"/> Chlorhexidine alcohol <input type="checkbox"/>	Hibitane <input type="checkbox"/> Hibiscrub <input type="checkbox"/> Chlorhexidine <input checked="" type="checkbox"/> Other <input type="checkbox"/>	



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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

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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: 03h00
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 	January 19, 2012 at 05 h 00 PM January 20, 2012 at 10 h 30 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 checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Fresh <input type="checkbox"/>	Frozen <input checked="" type="checkbox"/>
Other <input type="checkbox"/> /	
Surface	5 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 checked="" type="checkbox"/> <input type="checkbox"/>	No No No No	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	With hair



INTERNATIONAL

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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		February 17, 2012