SUBMISSION FORM - BIOCOMPATIBILITY ANALYSIS

to be sent prior to you shipment to Medistri SA at lab@medistri.swiss for biocompatibility analysis

ALL BOXES SHOULD BE FILLED OR N/A

CUSTOMER REFERENCES

Company's name		Your Reference (Delivery note or order)	
Contact person (your reference)		Phone	
E-mail address for sending of certificates		E-mail address for sending of invoices	
Address (street, n°)		PLZ / postcode, City, Country	

Information regarding the tests to perform

Type	Code	Choice	Sample
		Cytotoxicity Analysis are effected every Monday, Tuesday and Wednesday	Contact us for the indications below
Cytotoxicity	1006205 1006201 1006202	☐ XTT on extract ☐ Direct contact ☐ Indirect contact agar diffusion test	6 cm^2 or 0.2 g 6 cm^2 or 0.2 g 6 cm^2 or 0.2 g
Toxicology	1006061 1006071	☐ Chemical characteristics VOC/SVOC/NVOC ☐ Chemical Characteristics of inorganic elements	Approx. 3x60 cm^2 or 5 g Approx. 60 cm^2 or 5 g
Sensitization	1006210 1006209 1006208	☐ Buehler test ☐ Sensitization LLNA: local lymph node assay ☐ Maximization sensitization test	420 cm^2 or 7 g 3 x 35 cm^2 or 4 g 6x 90 cm^2 or 6 x 3 g
Irritation	1006211 1006212 1006226 1006227 1006228 1006229	☐ Intracutaneous irritation ☐ Dermal irritation ☐ Oral irritation ☐ Ocular irritation ☐ Vaginal irritation ☐ Intranasal irritation	2 x 30 cm^2 10x30 cm^2 10x30 cm^2 10x30 cm^2 200 cm^2 2x40 cm^2
Acute systemic toxicity	1006214	☐ Acute systemic toxicity	2 x 40 cm^2
Subacute systemic toxicity	1006215	☐ Subacute systemic toxicity	14 x 400 cm^2 ou 200 g
Toxicity caused by materials	1006213	☐ Pyrogen test	270cm^2
Genotoxicity	1006216 1006218 1006217 1006221 1006220 1006219 1006222	☐ Ames test (S. thyphimurium reverse mutation test ☐ Chromosome aberration test (Human Lymphocyte) ☐ Chromosome aberration test (V79 hamster cells) ☐ Micronucleus test in vitro (Human lymphocyte) ☐ Micronucleus test in vitro (V79 Chinese hamster ☐ Mouse Lyphoma test ☐ Micronucleus test in vivo (5 males and 5 females)	4 x 30 cm2 ou 4 x 1 g 2 x 1'200 cm^2 ou 2 x 40 g 2 x 1'200 cm^2 ou 2 x 40 g 2 x 1'200 cm^2 + 600 cm2 or 60 g 2 x 1'200 cm^2 + 600 cm2 or 60 g 2 x 1'200 cm^2 + 600 cm2 or 60 g 1 x 750 cm^2 and 1 x 2'250 cm^2 or 1 x 25 g and 1x 75 g or 2 x 240 cm^2
Hemocompatibility	1006224 1006225	☐ Hemolysis test ☐ Dynamic test	6 x 60 cm^2 or 6 x 2 g 5 samples
Implantation	1006223	☐ Implantation test	

ORDER DETAILS

☐ **Super express** Orders are processed upon receipt (working days), in priority and according to the minimum deadlines TAT (see price list). An additional 100% will be charged. Certificates are only released on working days.	☐ **express** Orders are processed upon receipt (working days), in priority and according to the minimum deadlines TAT (see price list). An additional 25% will be charged. Certificates are only released on working days.	☐ **standard** Orders are processed during business days, according to our analysis schedule Certificates are only released on working days.

Products(Exact number of samples to use for the pooltest)	☐ IT / individual tests ☐ PT / pooltest (precise the quantity of products)	Samples storage conditions	☐ room temperature (15 to 25° C) ☐ refrigerated (2 to 8° C) ☐ frozen (min. -20° C)	
Tests to be performed according to GLP (extra charge)	☐ yes ☐ no	Sterilisation conditions of samples	☐ non-sterile ☐ sterile ☐ sterilisation to be performed by Medistri SA (☐ EtO ☐ steam ☐ other :)	
Samples disposition after analysis	☐ discard ☐ return ☐ keep the samples during : _____ (nb days)	Have you received an offer from Medistri ? (if yes, please mention the offer reference n° ; if no, according to our price list)	☐ yes ☐ no	offer ref. n° #
Language of the final report	☐ english ☐ french	Certificate of analysis *	☐ one report for each sample ☐ one report per kind of analysis	

		Number of certificate required	Mandatory box to be filled out

INFORMATIONS REGARDING THE SAMPLES			
Product name		Product reference	
Manufacturing batch #		Product surface area in cm2	
Dimensions / weight		Quantity of sample submitted	
Physical description and composition of the product		Product special instruction for preparation and/or holding	
Product can be cut	☐ yes ☐ no	Type	☐ medical device ☐ pharmaceutical ☐ cosmetic ☐ other
Clinical use		Dangerous product (MSDS included)	☐ yes ☐ no
Stability period (Shelflife)			

SAFETY DECLARATION

Is there any chemical, hazard, toxic substances or explosive products inside your products / box ? ☐ NO ☐ YES

(**if yes**, please join the **Safety Data Sheet**, cross the concerned **pictogrammes** below and precise the **UN code** : _____)

Is there any drugs inside your products / box ? ☐ NO ☐ YES, What category: _____

Is there any pharmaceutical substances inside your products / box ? ☐ NO ☐ YES, Which Swissmedic, EFPIA, EMA or us-FDA code applies:

_____

If yes, please wait for Medistri's confirmation before sending your products / box !

Medistri has the right to refuse the delivery and / or the process of your products for security reasons.

Information relative the extraction of the product (if applicable)			
Extraction conditions	☐ 37°C/24 hours (for cytotoxicity) ☐ 37°C/72 hours (generally) ☐ N.A. ☐ Other	The extraction conditions are based on an exaggeration of product use (ISO-10993-12). For insoluble materials select the highest temperature that would not degrade the material	
Thickness and extraction ratio according to ISO 10993-12 (Only for solid product)	☐ < 0.5 mm ratio of 6 cm^2/mL ☐ > 0.5 mm ratio of 3 cm^2/mL ☐ Elastomeric closures 1,25cm^2/mL	Choose one of the following only if the surface area cannot be determined due to the shape of the product :	☐ 0.2 g/mL for irregulary shaped objects ☐ 0.2 g/mL for irregulary shaped porous objects

Characterization of the product (Pharma/AIMD, combination products only)					
Stability (before and after opening the packaging)	☐ yes ☐ no ☐ n.a. ☐ if no specify :	Active compounds in the product	☐ yes ☐ no ☐ n.a. ☐ if no specify :	Homogeneity	☐ yes ☐ no ☐ n.a. ☐ if no specify :
Composition			Purity		

FINALISATION AND SIGNATURE		
By signing the order form, the customer confirms that all the informations on this submission form are accurate and agrees with Medistri's general sales conditions (available on : www.medistri.com/en/general-terms-and-conditions)	**Date**	**Signature**

TO BE FILLED BY MEDISTRI SA ONLY					
Date de réception		Nombre de paquets reçus		Signature opérateur Medistri SA	
Heure de réception		Nombre d'échantillons reçus			
Etat des échantillons à la réception		☐ Bon état ☐ Dommage mineur ☐ Dommage majeur	Actions et plus-values		☐ Plus-value administrative ☐ Plus-value manipulation ☐ Envoi des photos des dommages au client (préciser la date :)

N° de labo-batch	

* In case of results supported by specific regulatory limits (chemical residues, biological response), the test is evaluated as “conform” if the result (including the measure uncertainty) is within the specified limits. The test is evaluated as “non-conform” for any other result (potentially non-conform or strictly non-conform).