MD GT-P-20-02/Rev.1
Creation date: 28/06/2023

CHEMOEXFOLIATION

ENERPEEL®

CE - CE 0373

COMPLICATIONS REPORT

Date of filling out the report __ __ / __ __ / __ __ __ __

DETAILS RELATED TO THE REPORTING DOCTOR

Name and surname: _____ Specialization: _____

Ambulatory / Hospital / Denomination: _____ Country: _____

Address: _____ City: _____ CAP: _____

E-mail: _____ Telephonic Ref: _____

DATA RELATED TO THE PATIENT AND HIS/HER MEDICAL HISTORY

Initials of the patient: ____ ____ Date of birth __ __ / __ __ / __ __ __ __ Gender: F M

PHOTOTYPE	☐ I	☐ II	☐ III	☐ IV	☐ V	☐ VI
ETHNICITY	☐ Nordics	☐ Europeans	☐ Mediterraneans	☐ Indo-Pakistan	☐ Africans	☐ Asians

DATA RELATED TO THE EXECUTED ENERPEEL® TREATMENT

Encountered Skin Problems: _____

_____

TYPE OF ENERPEEL® USED:			
☐ ENERPEEL® GA-70 solution containing glycolic acid (70%);	Batch: _____	☐ ENERPEEL® SA-CB Chest&Back solution containing salicylic acid (30%);	Batch: _____
☐ ENERPEEL® GA-50 solution containing glycolic acid (50%);	Batch: _____	☐ ENERPEEL® TCA solution containing trichloroacetic acid (25%);	Batch: _____
☐ ENERPEEL® GA-40 solution containing glycolic acid (40%);	Batch: _____	☐ ENERPEEL® TCA-LP (Less Pain) solution containing trichloroacetic acid (25%);	Batch: _____
☐ ENERPEEL® GA-30 solution containing glycolic acid (30%);	Batch: _____	☐ ENERPEEL® TCA STRONG solution containing trichloroacetic acid (40%);	Batch: _____
☐ ENERPEEL® PA solution containing pyruvic acid (50%);	Batch: _____	☐ ENERPEEL® NECK solution containing pyruvic acid (30%), lactic acid (10%), ferulic acid;	Batch: _____
☐ ENERPEEL® MA solution containing mandelic acid (40%);	Batch: _____	☐ ENERPEEL® HANDS solution containing trichloroacetic acid (20%), lactic acid (10%), kojic acid;	Batch: _____
☐ ENERPEEL® JR solution containing salicylic acid (15%), lactic acid (20%), resorcinol (14%);	Batch: _____	☐ ENERPEEL® EL solution containing trichloroacetic acid (3,75%), lactic acid (15%).	Batch: _____
☐ ENERPEEL® SA solution containing salicylic acid (30%);	Batch: _____	☐ ENERPEEL® EL-PLUS solution containing mandelic acid (20%), malic acid (15%), lactic acid (10%).	Batch: _____
☐ ENERPEEL® SA-15 solution containing salicylic acid (15%);	Batch: _____		

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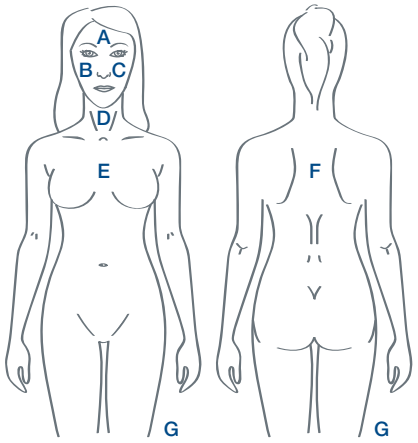
Peeling execution date: __ __ / __ __ / __ __ __ __

N°. of planned treatments:	N°. of the current treatment:	N°. of applied layers:	Application time before neutralization or removal of the precipitate:	☐ Neutralisation by ENERPEEL® NEU Neutralizer Wipes ☐ Removal of precipitate by ENERPEEL® RW Remover Wipes
_____	_____	_____	_____	

DESCRIPTION OF TREATED SKIN AREA		
☐ A	Forehead	
☐ B	Zygomatic portion of RIGHT cheek *(including the eye area, the nasogenian sulcus and the nasolabial portion)*	
☐ C	Zygomatic portion of LEFT cheek *(including the eye area, the nasogenian sulcus and the nasolabial portion)*	
☐ D	Neck	
☐ E	Decolletage	
☐ F	Back	
☐ G	Other parts of the body	

CONCOMITANT TREATMENTS

Other ongoing treatments related to the problem being treated (specify): _____

_____

Other ongoing treatments not related to the issue in question (specify): _____

_____

Followed protocol (specify the times between a treatment and the following): _____

_____

DESCRIPTION OF THE DETECTED COMPLICATION

Date of detection of the complication: __ __ / __ __ / __ __ __ __

Symptoms: _____

_____

CUTANEOUS AREA	☐ A	☐ B	☐ C	☐ E	☐ F	☐ G
SEVERITY	☐ Light	☐ Moderate	☐ Medium	☐ Severe		

Notes: _____

_____

Was there taken a photograph before the peel? Yes No
Please attach to this report copies of the photos taken

Was there taken a photograph after the peel? Yes No
Please attach to this report copies of the photos taken

EVALUATION OF THE CAUSES			
Method of application	☐ Probable	☐ Unlikely	☐ Not yet assessable
Type of ENERPEEL®	☐ Probable	☐ Unlikely	☐ Not yet assessable

Others (specify): _____

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CLASSIFICATION /SEVERITY OF THE COMPLICATION

The complication has caused a serious deterioration of health of a patient, user or other persons, such as:

Risk of illness or injury ☐ Yes ☐ No

Permanent impairment of a function or structure of the body ☐ Yes ☐ No

Death (if so, specify the date __ __ / __ __ / __ __ __ __) ☐ Yes ☐ No

METHOD OF TREATMENT OF THE COMPLICATION

Product/s and dosage used: _____

_____

_____

_____

Date __ __ / __ __ / __ __ __ __

_____
Stamp and signature of the reporting doctor

We kindly ask you to sign and stamp the original after you completed and printed the ENERPEEL® Complications REPORT form in its entirety. This form must be sent to GENERAL TOPICS s.r.l. via fax to 0365 75 22 619 or by e-mail to: regulatoryaffairs@general-topics.com or info@tebitech.com.

Explicit declaration: I undersigned Dr. _____ declare under my responsibility to communicate with this form truthful information. I discharge also General Topics s.r.l. from any direct and indirect responsibility resulting from improper use of the ENERPEEL® Medical Device.

Date __ __ / __ __ / __ __ __ __

_____
Stamp and signature of the reporting doctor

Authorization for the processing of personal data

Under the Regulation on Privacy (Regulation EU 2016/679 and following modifications/amendments) we inform you that your data will be stored in the Database owned by General Topics srl.These data will be used exclusively by General Topics s.r.l. with the sole purpose of internal handling. At any time you can request confirmation about the existence of personal data that concern you, ask for their deletion or oppose to their use. The patient details included in this form (initials, date of birth, gender) are provided by the doctor in order to identify, according to the information in his possession, the subject to whom they refer, but they do not constitute “confidential data” (c.d.) for General Topics S.r.l., as they lack the possibility of tracing back to the concerned party without the collaboration of the doctor, as autonomous data controller.

Date __ __ / __ __ / __ __ __ __

_____
Stamp and signature of the reporting doctor

RESERVED TO THE COMPANY

Report coming from (Country): _____ N. _____

Date __ __ / __ __ / __ __ __ __

_____
Signature AR

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