Casa di Cura
VILLA SERENA
Via V. Chiaruqi, 6 - 59100 PRATO

CLINICAL VALUATION REPORT

Medical device: **FABRIC WITH BIOMOLECULES**

1) RATIONAL STUDY

The clinical study described here was intended to evaluate the clinical efficacy and safety of the BIOMOLECULE FABRIC device.

2) DESIGN OF THE STUDY

The 8-week study, was conducted on 29 male and female subjects, aged between 33 and 85 years. The study was conducted in the period between 25/02/2015 and 20/04/2015 at VILLA SERENA REST HOUSE, in Prato.
Patients examined had the following symptoms and pathologies.

ID SAMPLES	PATHOLOGY	DEGREE/ SYMPTOMS	AREA	SEX	N° PATIENTS
A	Lower back Pain	Medium/ Serious	Lumbar	M/F	10
B	Cervical pain	Medium/ Serious	Cervical	F	10
C	Gonalgia	Medium	Knee	M/F	5
D	Impingement syndrome	Medium	Shoulder	M/F	4

To selected patients was applied 1 specimen of the device in the district that was suffering for a period of 30 days.
The conditions of the patients were reevaluated at a distance of 30 days after device apply.

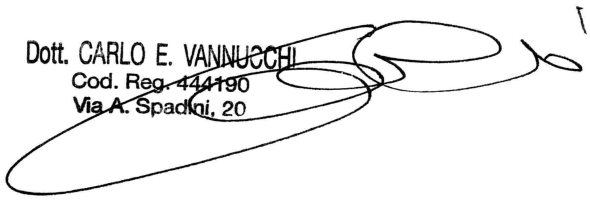
3) RESULTS

The results of treatment with reference to the standard of table 1, are briefly summarized in the following table.

ID SAMPLE	N° IMPROVED PATIENTS	N°STABLE PATIENTS	N° WORSENED PATIENTS	NOTES
A	80,00%	20,00%	0	/
B	80,00%	20,00%	0	/
C	80,00%	20,00%	0	Stable patients have reported improvement in

				the first few days and then no change
D	50,00%	50,00%	0	See notes above

4) CONLUSIONS
On the basis of the results referred to in Table 2 it can be concluded that the BIOMOLECULES FABRIC device is effective and well tolerated.



CLINICAL VALUATION REPORT

Medical device: **FABRIC WITHOUT BIOMOLECULE**S

1) RATIONAL STUDY

The clinical study described here had the purpose to evaluate the effectiveness of a similar product but devoid of the active and clinically tested feature.

2) DESIGN OF THE STUDY

The 8-week study, was conducted on 29 male and female subjects, aged between 33 and 85 years. The study was conducted in the period between 25/02/2015 and 20/04/2015 at VILLA SERENA REST HOUSE, in Prato.
Patients examined had the following symptoms and pathologies.

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3) RESULTS

The results of treatment with reference to the standard of table 1, are briefly summarized in the following table.

ID SAMPLE	N° IMPROVED PATIENTS	N°STABLE PATIENTS	N° WORSENED PATIENTS	NOTES
A	0,00%	90,00%	10,00%	/
B	0,00%	100,00%	0	/
C	5,00%	85,00%	0	/
D	0,00%	80,00%	20,00%	/