Istituto Antonio Ricci
V.le G. Parenti, 22/24 - 59015 Carmignano (PO)

CLINICAL VALUATION REPORT

Medical device: fabric **WITH BIO-MOLECULES**

1) RATIONAL STUDY
The clinical study described here was intended to evaluate the clinical efficacy and safety of the BIO-MOLECULES LOADED device.

2) STUDY DESIGN
The study lasts 11 weeks, was conducted on 28 male and female subjects aged between 55 and 85 years.

The study was conducted between 26th of February 2015 and 8th of April 2015 at "Instituto RICCI" in Carmignano, Prato.

Patients examined had the following symptoms and diseases.

ID SAMPLE	PATHOLOGY	DEGREE/ SYMPTOMS	SEX	N° PATIENTS
1	Osteoarthritis	Medium/Serious	M/F	20
2	Gonarthrosis	Medium/Serious	F	3
3	Sciatica	Medium/Serious	F	5

The patients applied 1 sample of the device in the district that presented the suffering, for a 30 days period.
The conditions of the patients were reevaluated after 30 days from the device apply.

3) RESULTS
The results of the treatment, with reference to the sample of the Tab. 1 are succinctly summarized in the following table.

ID SAMPLES	N° IMPROVED PATIENTS	N° STABLE PATIENTS	N° WORSENED PATIENTS	NOTES
1	90,00%	10,00%	0,00%	Pain significatly decreased
2	100,00%	0,00%	0,00%	Pain significatly decreased

3	80,00%	20,00%	0,00%	Pain significatly decreased

4) CONCLUSIONS
On the basis of the results of Tab. 2 it can be concluded that the BIO-MOLECULE LOADED device is effective and well tolerated.

CLINICAL VALUATION REPORT

Medical device: fabric **WITHOUT BIO-MOLECULES**

1) RATIONAL STUDY

The clinical study described here was intended to evaluate the efficacy of a similar product, devoid of clinically tested feature.

2) STUDY DEDIGN

The study lasts 11 weeks, was conducted on 28 male and female subjects aged between 55 and 85 years.

The study was conducted between 26th of February 2015 and 8th of April 2015 at “Instituto RICCI” in Carmignano, Prato.

Patients examined had the following symptoms and diseases.

ID SAMPLE	PATHOLOGY	DEGREE/ SYMPTOMS	SEX	N° PATIENTS
1	Osteoarthritis	Medium/Serious	M/F	20
2	Gonarthrosis	Medium/Serious	F	3
3	Sciatica	Medium/Serious	F	5

The patients applied 1 sample of the device in the district that presented the suffering, for a 30 days period.
The conditions of the patients were reevaluated after 30 days from the device apply.

3) RESULTS
The results of the treatment, with reference to the sample of the Tab. 1 are succinctly summarized in the following table.

ID SAMPLES	N° IMPROVED PATIENTS	N° STABLE PATIENTS	N° WORSENED PATIENTS	NOTES
1	5,00%	95,00%	0,00%	/
2	0,00%	97,00%	3,00%	/
3	0,00%	90,00%	10,00%	/

Timbro e Firma