15 January 2025

To whom it may concern,

MedOne Surgical products are manufactured in a facility that utilizes solar energy for a portion of its energy needs. As a result, renewable energy sources are used to produce the products. MedOne is proud of our efforts to conserve energy and utilize renewable sources of energy in the manufacture of our products.

Sincerely,

Bruce Beckstein
President

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Declaration of Compliance

10.02.2020

We hereby declare that none of the products that we produce does not contain any drug, human blood or animal tissue derivative.

We hereby declare that none of the products does not contain any phthalates derivatives.

Reference:

COMMISSION REGULATION (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilizing tissues of animal origin

Kind regards,

Teknomek Medikal Malz. San. Ve Tic. Ltd. Şti.

PREPARED BY	APPROVED BY
	

1. PURPOSE

The aim of this report is to evaluate whether the chemicals in the product that come into contact with the body and product's packaging materials are hazardous substances as per Regulation (EC) No 1272/2008 and Regulation (EC) No 1907/2006 according to Article 10.4 in (EU) 2017/745 Medical Device Regulation.

2. SCOPE

This report includes Perfluorodecaline product group and its hazardous substances evaluation.

3. REFERENCES

- Medical Device Regulation, Regulation (EU) 2017/745
- Regulation (EC) No 1272/2008 of the European Parliament and of the Council
- Regulation (EC) No 1907/2006 of the European Parliament and of the Council

4. IMPLEMENTATION

4.1.Products and Raw Materials

The product's raw materials have direct contact with the intraocular tissue are evaluated according to Part 3 of Annex VI to Regulation (EC) No 1272/2008 if the product contains the substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'). Evaluation is also made accordance with Article 59 of Regulation (EC) No 1907/2006 if the product contains the substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health.
Perflurodecaline does not contain phthalates derivatives, the declaration is available in TF.12-18 Declaration of Compliance.

The product, raw material, supplier information and CAS No can be seen in the Table 1. The raw material's CAS No was searched in 1272/2008 Regulation and 1907/2006 Regulation, and evaluation was made about existence.

Product	Raw Material	Supplier	CAS No	1272/2008 Regulation	1907/2006 Regulation	Acceptance
Perfluorodecaline	Octadecafluorodecahydronaphthalene	[redacted]	306-94-5	Not exist	Not exist	Acceptable

Table 1: Product, raw material, supplier information and CAS No

4.2.Packaging Materials

The packaging materials have indirect contact with the intraocular tissue, that can leach from packaging are evaluated according to Part 3 of Annex VI to Regulation (EC) No 1272/2008 if the packaging material contains the substances which are carcinogenic,

mutagenic or toxic to reproduction ('CMR'). Evaluation is also made in accordance with Article 59 of Regulation (EC) No 1907/2006 if the packaging material contains the substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health.

Packaging Material	Raw Material		Supplier	CAS No	1272/2008 Regulation	1907/2006 Regulation	Acceptance
Glass Vial Lid	Butyl		[redacted]	NA	Not exist	Not exist	Acceptable
Glass Vial Bottle 8R	Type 1 Brosilicate		[redacted]	NA	Not exist	Not exist	Acceptable
			[redacted]	NA	Not exist	Not exist	Acceptable
10 ml Glass Syringe Barrel With Luer Lock	Type I Borosilicate Glass		[redacted]	NA	Not exist	Not exist	Acceptable
Plunger Stopper	Elastomer		[redacted]	NA	Not exist	Not exist	Acceptable
LLA Collar of Luer Lock (Plastic rigid tip cap)	Polycarbonate		[redacted]	NA	Not exist	Not exist	Acceptable
RiTC of Luer Lock (Plastic rigid tip cap)	Isoprene-Bromobutyl		[redacted]	NA	Not exist	Not exist	Acceptable
[redacted] ROLL	Propypel for white paper PP/PE for Lamine Film	Medical paper*** *	[redacted]	NA	Not exist	Not exist	Acceptable
		Polyester		25038-59-9	Not exist	Not exist	Acceptable
		PP Film		9003-07-0	Not exist	Not exist	Acceptable
[redacted] ROLL	Propypel for white paper PP/PE for Lamine Film		[redacted]	NA	Not exist	Not exist	Acceptable

Table 2: Packaging material, supplier information and CAS No

*[redacted]i does not have raw material's CAS No and MSDS, the mail is in Annex 1.

*[redacted] states that the material does not have CAS No, the mail is available in Annex 2.

**[redacted] has sent the Materials Of Concern And Safety Information for each packaging raw material. In those documents, [redacted] has not identified any chemicals in the product in an individual concentration above 0.1% weight by weight (w/w) according to Art.59 of the Regulation (EC) No 1907/2006 and part 3 of Annex VI to Regulation (EC) No 1272/2008. The Materials of Concern and Safety Information documents are available in Annex 3.

*** [redacted] states that the medical paper of PMS roll does not have CAS No, the mail is in Annex 4.

***** [redacted] mentions that the sterintech roll does not have CAS No, the conversation with the company is in Annex 5.

5. CONCLUSION

Product's raw materials and packaging materials are evaluated in accordance with Regulation (EC) No 1272/2008 and Regulation (EC) No 1907/2006, Article 10.4 in (EU) 2017/745 Medical Device Regulation. Materials are not classified as hazardous and does not contain substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR') or endocrine-disrupting properties.