

Date: 28-03-2023

To whomsoever it may concern

Subject: A declaration stating that the pH value of Surgi-ORC[®] (Oxidized Regenerated Cellulose Haemostat)

We, Aegis Lifesciences Pvt. Ltd., located at 215/216, Mahagujarat Industrial Estate-382213, Ahmedabad, Gujarat, India, are the manufacturer of the finished product as mentioned below

1. Surgi-ORC[®] (Oxidized Regenerated Cellulose Haemostat) along with all variants & sizes.

As manufacture of the product, we hereby declare that the pH determination test of the product Oxidized Regenerated Cellulose Haemostat was carried out in our facility with reference to USP <791> and by taking 10 samples in triplet set, at temperature 37±1°C.

The result of performed test, concluded that the Surgi-ORC[®] (Oxidized Regenerated Cellulose Haemostat) is having highly acidic characteristic in pH range of 2.5 to 3.5.

Signature



Mr. Vivek Kumar Shahi

Regulatory Affairs Assistant

Aegis Lifesciences Pvt. Ltd.

Place: Ahmedabad, India