Change Authorised (Signatures as applicable (master copy only))		
Opera-tions	Name: P. Curtis	Date: 07/01/2020
	Signature:	
QA	Name: J. Andrews	Date: 07/01/2020
	Signature:	

Revision Control:
If there is need for revision the table below will be updated with the new revision number, date and any changes made

REV	DATE	DESCRIPTION OF CHANGE
10	16/05/18	Added front page change control document. Zorflex LA dressings added. Retention time of 5 yrs plus the lifetime of the product changed to 10 Years
11	17/07/19	Re signed due to the addition of a new sterilisation facility. No other changes made
12	07/01/2020	SGS updated from SGS UK to SGS Belgium. Retention time adjusted

Copies Located:
The location of all distributed copies shall be recorded in the table below

Date	Location
07/01/2020	Quality Drive

1. Activated Carbon Cloth Medical Dressings for Human Use

This declaration refers to the following Class IIb

Intended for wounds which breach the dermis and heal by secondary intent (eg. Pressure Ulcers, venous ulcers, diabetic ulcers).

Sterile Medical Devices which are supplied for human use and are to be exported within the member states:

1.1 Derivatives for Human Use and Sterile

Product Description	Product Code	Size
Zorflex	**ZF05**	**5cm x 5cm**
	ZF10	**10cm x 10cm**
	ZF15	**15cm x 25cm**
	ZF20	**20cm x 10cm**
Zorflex LA	**ZLA10**	**10.5cm x 10.5cm**
	ZLA15	**15cm x 25cm**
	ZLA20	**20cm x 10cm**

These devices do not incorporate any substances referred to in Section 7.4 of Annex I of 93/42/EEC.

The device is not manufactured with and does not incorporate any substances of animal origin.

The aforementioned Medical Devices are controlled through the implementation and maintenance of the following Quality Systems:

BS EN ISO 9001

BS EN ISO 13485

And conform to the requirements of:

Council Directive 93/42/EEC - with Annex II

2. Notified Body

2.1 This Quality System shall be monitored and audited by:
S.G.S. Belgium NV
SGS House
Noorderlaan 87
Antwerp
2030
Belgium

No application shall be lodged with any other Notification Body for these products.

3. Technical Documentation

3.1 All Technical Documentation relating to the aforementioned devices, as stipulated in Annex II of the 93/42/EEC directive shall be held at the manufacturers premises at:

Chemviron Carbon Cloth Division,
A Division of Chemviron Carbon Ltd
Rainton Bridge Industrial Estate
Houghton-le-Spring,
Tyne and Wear,
England,
DH4 5PP.

3.2 This Technical Documentation shall be retained for a minimum of five years after the last date of manufacture.

3.3 The aforementioned devices shall be reviewed periodically by following the relevant procedures outlined in the Quality System.

In the event of any occurrences arising as outlined in Annex II, Section 4, of the Directive 93/42/EEC the Competent Authority for the member states shall be informed immediately on Chemviron Carbon Cloth Division learning of them.

Signed : 

Position : Operations Manager

Date: 07/01/2020