
Certificate of Approval

This is to certify that the Management System of:

AMPACET EUROPE S.A.

Z.A.E. Wolser H 130,, 3451 Dudelange, Luxembourg

has been approved by LRQA to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00052181

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Design, Manufacturing and sales of color and additive masterbatches and compounds for use in pharmaceutical packaging, medical and diagnostic devices.



Marta Escudero

Regional Director, Europe

Issued by: LRQA Limited



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Certificate Schedule

Location	Activities
AMPACET EUROPE SA Z.A.E. Wolser H 130,, 3451 Dudelange, Luxembourg	ISO 13485:2016 Design and sales of color and additive masterbatches and compounds for use in pharmaceutical packaging, medical and diagnostic devices.
AMPACET ITALIA S.r.l. Via Dante Alighieri, 42, 24041 BREMBATE, Italy	ISO 13485:2016 Manufacturing of color and additive masterbatches and compounds for use in pharmaceutical packaging, medical and diagnostic devices.



Certificat d'Approbation

Nous certifions que le Système de Management de la société :

AMPACET EUROPE S.A.

Z.A.E. Wolser H 130,, 3451 Dudelange, Luxembourg

a été approuvé par la société LRQA selon les normes suivantes :

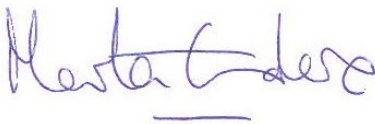
ISO 13485:2016

Numéro(s) d'approbation : ISO 13485 – 00052181

Ce certificat n'est valable que s'il est accompagné de l'annexe portant le même numéro, et sur laquelle figure la liste des sites correspondant à l'approbation.

Le Système de Management concerne :

Conception, fabrication et commercialisation de masterbatches et de compounds de couleur et d'additifs destinés à être utilisés dans les emballages pharmaceutiques, les dispositifs médicaux et les dispositifs de diagnostic.



Marta Escudero

Regional Director, Europe

Emis par : LRQA Limited



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Annexe au certificat

Site	Activités
AMPACET EUROPE SA Z.A.E. Wolser H 130,, 3451 Dudelange, Luxembourg	ISO 13485:2016 Conception et commercialisation de masterbatches et de compounds de couleur et d'additifs destinés à être utilisés dans les emballages pharmaceutiques, les dispositifs médicaux et les dispositifs de diagnostic.
AMPACET ITALIA S.r.l. Via Dante Alighieri, 42, 24041 BREMBATE, Italie	ISO 13485:2016 Fabrication de masterbatches et de compounds de couleur et d'additifs destinés à être utilisés dans les emballages pharmaceutiques, les dispositifs médicaux et les dispositifs de diagnostic.



Certificato di Approvazione

Si certifica che il sistema di gestione di:

AMPACET EUROPE S.A.

Z.A.E. Wolser H 130,, 3451 Dudelange, Lussemburgo

è stato approvato da LRQA per conformità alle seguenti norme:

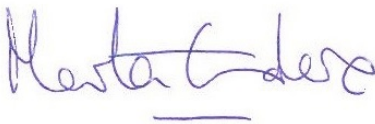
ISO 13485:2016

Numeri di Approvazione: ISO 13485 – 00052181

La validità di questo certificato è vincolata all'allegato dello stesso numero che elenca i siti oggetto dell'approvazione.

Lo scopo di questo certificato si applica a:

Sviluppo, produzione e vendita di Masterbatch and Compound colori e additivi per utilizzo nel confezionamento farmaceutico, in dispositivi medici e diagnostici.



Marta Escudero

Regional Director, Europe

Emesso da: LRQA Limited



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Certificato di Approvazione

Ubicazione	Attività
AMPACET EUROPE SA Z.A.E. Wolser H 130,, 3451 Dudelange, Lussemburgo	ISO 13485:2016 Sviluppo e vendita di Masterbatch and Compound colori e additivi per utilizzo nel confezionamento farmaceutico, in dispositivi medici e diagnostici.
AMPACET ITALIA S.r.l. Via Dante Alighieri, 42, 24041 BREMBATE, Italia	ISO 13485:2016 Produzione di Masterbatch and Compound colori e additivi per utilizzo nel confezionamento farmaceutico, in dispositivi medici e diagnostici.

