



Summary of the Pharmacovigilance System Master File

EV Code: MFL8547

10.04.2018

S Ahlen Medical Nordic AB as Marketing Authorization Holder/Applicant declares to:

- **have at its disposal a qualified person responsible for pharmacovigilance (QPPV) who resides and carries out tasks in Sweden:**

*Rossetti Tran
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131 26 Nacka Strand, Sweden
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E-mail: rossetti.tran@samnordic.se*

- **have necessary means to fulfill the tasks and responsibilities listed in Title IX of Directive 2001/83/EC as described in Pharmacovigilance System Master File located at:**

SciencePharma

Chelmska 30/34, 00-725 Warsaw, Poland.

Once the Article 57 database is functional, changes in QPPV, including contact details and changes to the location of the PSMF will be updated through the Article 57 database only. I hereby confirm that the information of those particulars, included in the Article 57 database, is correct and up-to-date.

On behalf of S Ahlén Medical Nordic AB,
Isabell Ahlén
CEO

QPPV of S Ahlén Medical Nordic AB,
Rossetti Tran
QA MANAGER / RP / QPPV